

Plan for Diverse, Equitable, and Inclusive Engagement

What should I do?

Start with inclusive engagement. Develop a more inclusive outreach and engagement plan with a process for continuous engagement to encourage and support participants for retention. Inclusivity allows for meeting all participants where they are, with what they need to participate fully.

Why should I do it?

- Increase access and awareness for participants to clinical trial participation.
- Increase access and knowledge, for clinical trial designers and implementers, to diverse populations.
- Increase and improve patient engagement and retention.
- Reduce burdens for participants and clinical trial teams by streamlining and creating efficiencies with awareness and outreach.
- Build trust by demonstrating interest in working directly with diverse communities.

Ethical Considerations

Inclusivity means that all participants feel comfortable and have the resources they need to fully participate throughout the clinical trial process. This begins with participant engagement. These recommendations should be used as a starting point and then customized for specific diverse populations or geographic areas. Each community has specific experiences with the clinical trial or research industries. Deliberate and informed actions should be taken to ensure harms are not perpetuated. When using digital tools, specific attention should be paid to access and competency levels.

Jump to:

- [Engage for Diversity, Equity, and Inclusion](#)
- [Be intentional and granular for optimal engagement](#)
- [Digital Readiness Assessment](#)
- [Inclusive Communications Guide](#)

Clinical trial success is dependent on enrolling and retaining all populations that stand to benefit from the drug or product under investigation. This means **designing and implementing intentional strategies to engage** diverse populations coupled with actions to ensure all participants feel included and comfortable to participate fully.

Several digital tools can be utilized in the inclusive engagement plan including a digital companion app, digital campaign, on demand videos, virtual visits, and additional digital solutions. See the “[Elements of a Diverse, Equitable, and Inclusive Digital Clinical Trial](#)” for details on applicability of these tools.

Engage for

Diversity	Equity	Inclusivity
<p>Do: Identify which populations are most affected by the health condition you are studying.</p>	<p>Do: Include diverse populations even if data on the health condition is not predominantly associated with that population. This may be due to insufficient data.</p>	<p>Do: Establish partnerships with relevant community and patient advocacy groups for sustainable clinical trial success. Enlist participants as partners.</p>
<p>Do: Consult multiple RWD/RWE sources.</p>	<p>Do: Recognize that many populations have been underserved or underrepresented in many datasets.</p>	<p>Do: Implement a multi-directional and mutually supportive engagement strategy, with participants, for shared decision making and innovation.</p>
<p>Do: Create multiple campaigns, specific to different populations and communities.</p>	<p>Do: Recognize that one size does NOT fit all. Invest resources in learning about each community or group you need to engage.</p>	<p>Do: Provide opportunities for participants to actively give feedback before the trial begins, such as establishing a participant advisory board. Include patients, caregivers, and community leaders.</p>



Be intentional and granular for optimal engagement



Do

- Meet participants where they are for access to digital technologies.
- Meet participants where they are for their confidence level with using digital technologies.



Don't

- Do not expect that everyone has access to high-speed internet, wifi, or know how to use bluetooth pairing.
- Do not assume that all participants will know how to use every or any digital tools just because they have a smartphone.

Use the [Digital Readiness Assessment](#)

- Use representative populations in your digital campaigns (videos, social media, email, newsletters) and develop storylines specific to each population.
 - Include representative populations when designing and developing engagement campaigns to ensure that you are demonstrating respect for each culture. Conduct robust user testing.
 - Develop strong partnerships with community leaders and work with them to go out and reach different populations.
 - Design a full experience for participants that fits within their current lifestyle.
 - Design outreach, engagement, and product materials at different reading levels.
 - Develop a process for participants to become partners, e.g. participant advisory board. Learn from them and use that to innovate for future trials.
- Do not only use diverse populations for the cover images. If your digital ad has a black woman for breast cancer the associated link leading to your website should also show black women.
 - Do not assume that you know the lived experiences of others and can represent them.
 - Do not expect participants to come to you.
 - Do not expect participants to reconfigure their lives to fit into your clinical trial.
 - Do not expect to drop in and out as suits your needs, i.e. providing a smartphone to participate in the trial and then taking it away after the trial is over.
 - Do not assume that all participants can comprehend your trial materials.
 - Do not treat participants as only patients, who you are administering a treatment to. Do not underestimate the great value from their lived experiences.





Do



Don't

Use the [Inclusive Communications Guide](#)

- Design outreach, engagement, and product materials for different visual preferences (for example, more images instead of text, or videos in addition to print materials).
 - Translate all materials, including informed consent, into different languages to allow for easier participation of diverse populations.
 - Provide multiple mechanisms for potential participants to express interest in your trial (phone, email, online sign up, QR code, on site).
 - Provide support customized to different groups; clinical trial staff should be diverse and representative of the intended participant pool and be able to communicate in the participant's preferred language or mechanism.
- Do not assume all participants can consume materials in the same way.
 - Do not assume that all participants speak English or are comfortable communicating in English.
 - Do not expect that all participants are comfortable using one mechanism, such as signing up online.
 - Do not rely on translation services or assume that everyone is at the same level of fluency for English.





References & Resources

1. [Are Your Digital Tools an Unintended Barrier to Diversity in Research? How to Bridge the Technology Gap for Research Participants](#). Details on innovative digital solutions to meet participants where they are while continuing to run a digital research program.
2. [CDC Health Equity Guiding Principles for Inclusive Communication](#)
 - a. [Inclusive Images](#)
 - b. [Health Equity Considerations for Developing Public Health Communications](#)
3. [Diversity, Inclusion, and Equity in Clinical Research](#). This toolkit provides general information and practical resources (logic models, KPI, checklists) to develop plans for more diverse representation in clinical research.
4. [Elements of Informed Consent](#). Guides for ensuring that your informed consent are at the appropriate reading level.
5. [Health Equity Guiding Principles for Inclusive Communication](#). CDC guidance on communicating for health equity.
6. [How to Use CHI's Public and Patient Engagement Budgeting Tool](#). This is a free budgeting tool to assist with creating an inclusive patient and community engagement plan.
7. [Medical Illustrations Working Toward Health Equity](#). Here's a look at a medical illustration and perception issues and solutions working toward diverse representation for all.
8. [Methods of Patient and Public Engagement](#). This guide helps you decide which participatory approach to apply to your engagement strategy.
9. [Patient Engagement Guide for Sponsors and Contract Research Organizations \(CROs\)](#). This provides the business case and resources for patient engagement, specifically with clinical trials.
10. [Readiness to Engage Workbook](#). This is a free online tool to help plan engagement activities for patients and communities.
11. [Social media and clinical trials: The pros and cons gain context when the patient is at the center](#). Social media is a useful tool for increasing awareness and disseminating information about clinical trials, but includes risks.
12. [To Create a Diverse Research Participant Population, Start with These Strategies](#). Without understanding what a truly equitable participant population looks like, you will struggle to understand if you've successfully achieved your goal.
13. [Unlocking Scientific Research for Lay Audiences](#). Putting Recommendations for Plain Language Summaries into Practice





Resource Appendix: Digital Readiness Assessment

- Use this digital assessment to determine the level of assistance needed by participants. You can customize it for engagement and for use with all digital health tools.
- This tool should be integrated into your participant engagement materials and your study design.
- This tool will support you with preparing your participants for success, and contribute to building trust that can result in long-term product use and successful outcomes.
- This tool was designed as one component of the [Digital Health Measurement Collaborative Community Toolkit for Inclusive Deployment](#), where you can also find additional inclusivity toolkits.

Participant Assessment

Instructions | Please answer all questions as best as possible. Mark an X or circle your answer. Let us know if you have any questions.

Name: _____

1. Do you own any of these devices?

- | | | |
|--------------------|---------------------------|--------------------------|
| a. Smartphone | <input type="radio"/> Yes | <input type="radio"/> No |
| b. Tablet | <input type="radio"/> Yes | <input type="radio"/> No |
| c. Computer | <input type="radio"/> Yes | <input type="radio"/> No |
| d. Cell phone only | <input type="radio"/> Yes | <input type="radio"/> No |
| e. Landline | <input type="radio"/> Yes | <input type="radio"/> No |

2. How often do you use each device?

- | | | | | |
|---------------|-----------------------------|------------------------------|-------------------------------|-----------------------------|
| a. Smartphone | <input type="radio"/> Daily | <input type="radio"/> Weekly | <input type="radio"/> Monthly | <input type="radio"/> Never |
| b. Tablet | <input type="radio"/> Daily | <input type="radio"/> Weekly | <input type="radio"/> Monthly | <input type="radio"/> Never |
| c. Computer | <input type="radio"/> Daily | <input type="radio"/> Weekly | <input type="radio"/> Monthly | <input type="radio"/> Never |



3. In the past week, which device have you used to do the following?

- a. Texting Smartphone Tablet Computer None
- b. Voice calls Smartphone Tablet Computer None
- c. Video calls Smartphone Tablet Computer None
- d. Emails Smartphone Tablet Computer None
- e. Search the internet Smartphone Tablet Computer None
- f. Download an app Smartphone Tablet Computer None
- g. Install an app Smartphone Tablet Computer None
- h. Watch videos Smartphone Tablet Computer None

4. Where do you use the internet and on which device?

- a. Home Smartphone Tablet Computer
- b. Friend/family's home Smartphone Tablet Computer
- c. School or work Smartphone Tablet Computer
- d. Public library Smartphone Tablet Computer
- e. Coffee shop/restaurant Smartphone Tablet Computer
- f. Other public space Smartphone Tablet Computer

5. How comfortable are you with doing the following on your smartphone?

- a. Turning it on or off Very Somewhat Not at all
- b. Texting Very Somewhat Not at all
- c. Connecting to the internet Very Somewhat Not at all
- d. Searching the internet Very Somewhat Not at all
- e. Connecting to Bluetooth Very Somewhat Not at all
- f. Making video calls Very Somewhat Not at all
- g. Downloading apps Very Somewhat Not at all
- h. Installing updates Very Somewhat Not at all



- i. Taking photos Very Somewhat Not at all
- j. Sharing photos Very Somewhat Not at all
- k. Watching videos Very Somewhat Not at all
- l. Adjusting security settings Very Somewhat Not at all

**6. How comfortable are you with doing the following on a computer or tablet?
You may skip this question if you do not have a computer or tablet.**

- a. Turning it on or off Very Somewhat Not at all
- b. Logging on with a password Very Somewhat Not at all
- c. Connecting to Bluetooth Very Somewhat Not at all
- d. Connecting to internet Very Somewhat Not at all
- e. Using a mouse or keyboard Very Somewhat Not at all
- f. Searching the internet Very Somewhat Not at all
- g. Using email Very Somewhat Not at all
- h. Setting bookmarks Very Somewhat Not at all
- i. Making video calls Very Somewhat Not at all
- j. Downloading apps Very Somewhat Not at all
- k. Downloading information Very Somewhat Not at all
- l. Installing updates Very Somewhat Not at all
- m. Staying safe online Very Somewhat Not at all
- n. Adjusting security settings Very Somewhat Not at all
- o. Contacting tech support Very Somewhat Not at all

7. How concerned are you about the following?

- a. Internet access at home Very Somewhat Not at all
- b. Internet access at home for



- multiple devices or users Very Somewhat Not at all
- c. Cost of internet access Very Somewhat Not at all
- d. Sharing information online Very Somewhat Not at all
- e. Using digital devices Very Somewhat Not at all
- f. Finding assistance online Very Somewhat Not at all

8. Have you interacted with healthcare professionals through any of these devices?

- a. Smartphone Yes No
- b. Tablet Yes No
- c. Computer Yes No
- d. Cell phone only Yes No
- e. Landline Yes No
- f. Patient portal Yes No
- g. Social media Yes No



Resource Appendix: Inclusive Communications Guide

- Use this guide to develop clear communication materials for all participant facing materials. It should be used early in the planning process, when developing public-facing materials, and should be consulted throughout the clinical trial life cycle.
- This tool will support you with preparing your participants for success, and contribute to building trust that can result in long-term product use and successful outcomes.
- This tool was designed as one component of the [Digital Health Measurement Collaborative Community Toolkit for Inclusive Deployment](#), where you can also find additional inclusivity toolkits.

Clear Communication Materials are Essential for Inclusion

One way to build trust with participants and community is with clear communications. Taking time to be more inclusive with your message and **meeting participants where they are** will allow for more effective communications, better workflows, improved adherence, and better outcomes.

Plain Language for Digital Inclusion

1. Focus the message to your audience - provide a simple, easy-to-understand purpose of your work to customize your message to your intended users. **Start with the key takeaway for your audience.** Community partners can help with identifying elements that are important to your audience, within the scope of your digital health product.
 - a. Address the user with pronouns; this draws the user's attention to the specific information being shared. Confirm the user's preferred pronoun as early as possible.
 - b. Use an active voice to clearly identify the action in your message. Active voice is more similar to spoken language and is therefore easier to understand.
2. Be concise and organize the flow of information - do not overwhelm your audience with too much information. Try to limit each communication to **four to six key messages.**
 - a. Use subheadings to organize the information and preview the content to follow.



- b. Use bullets to highlight key pieces of information.
 - c. Use numbering if you need your audience to follow steps; this will help them mentally organize and visualize the process.
 - d. Use bold, underline or italics to emphasize key points, without being overwhelming.
3. **Write at a 7-8th grade level** - The average U.S. adult reads at a 7th-8th grade level. According to the American Medical Association, the National Institutes of Health and the Centers for Disease Control and Prevention, medical information should be written at less than 8th grade reading level. Readability analysis can be conducted directly with Microsoft Word or with an [online readability calculator](#).
- a. The Flesch Reading Ease formula will output a number from 0 to 100 - a higher score indicates easier reading. Aim for a number above 75; scores of 90-100 can be understood by an average 5th grader, 60-70 corresponds to 8th and 9th grade students, and 0-30 for college graduates.
 - b. The Flesch-Kincaid Grade Level outputs a U.S. school grade level (1-16); this indicates the average student in that grade level can read the text. A score of 7.4 indicates that the text is understood by an average student in the 7th grade.
4. **Use Visuals** (images, infographics, diagrams): visual representations are more inclusive than text and allow for deeper understanding of the information. The [Visualizing Health Project](#) developed a free online tool to help identify when and how to use images when sharing health information.
5. **Avoid jargon and acronyms:** avoid using subject area-specific vocabulary; use words that are familiar to your audience. If acronyms are necessary, use them only after they have been defined, and do not assume your audience will remember acronyms even after they have been defined. Include a glossary of important terms and acronyms if they are essential to the digital product use. See [CDC's Everyday Words for Public Health Communication](#).

This tool was adopted from the following resources

1. [Elements of Informed Consent](#). Guides for ensuring that your informed consent are at the appropriate reading level.
2. [A Plain Language Checklist for Health Care Professionals](#). A checklist for health care professionals to evaluate verbal and written materials.



3. [Health Equity Guiding Principles for Inclusive Communication](#). CDC guidance on communicating for health equity.

Examples of Inclusive Language

Project Background - Original Text

Extensive analysis of airway flow and physiology is needed to better understand how communities in cities are impacted. A research team from the UCNH will establish community partnerships to conduct new pulmonary research, utilizing a novel digital health technology. This translational research investigation will utilize a smartphone app to measure the cough reflex associated with asthma and identify correlations between reflex function and the patient's quality of life. The Achoo Microphone app is accessible on iOS and Android devices. The purpose of this work is to better understand how well this microphone works to detect a cough associated with asthma and use additional health information to understand if there are any associations with the person's quality of life. This product was previously tested on 100 people with asthma, in a laboratory. Therefore, we are testing real-world scenarios to determine if the product is effective.

The goals laid out for this project will augment existing data on the use of this microphone app by collecting additional data from people with and without asthma, and identifying additional health factors or quality of life factors that may contribute to worsening asthma outcomes. Anticipated outcomes include more data on the app use for people with asthma, new data on the app use for people without asthma, and data on quality of life and how they affect asthma outcomes. The data will be published in peer-reviewed academic journals and presented at international research conferences.

Recruitment will be limited to those living in New Haven, CT, presenting with a medical diagnosis of asthma. New Haven residents without asthma will serve as matched controls. Participants will use this digital health product for one year, and share data collected by the app. While this investigation will focus on coughing, the app will also collect activity data for steps, flights of stairs climbed, walking speed, and mobility. Additionally, users will be asked to record information on daily life activities. Cough data will be assessed for cough volume and frequency. Lifestyle information will allow the research team to analyze the cough data in the context of daily activities.

This text above is at a Flesch Reading Ease score: **33.1** and Flesch-Kincaid Grade Level: **14.1**. That means it is difficult to read and is written for those with at least some college education.



More Inclusive Content - Improved Readability

We want to know if where you live makes your asthma worse. We are from the University College of New Haven (UCNH) and will study a new phone app, called Achoo Microphone. The app will allow us to learn about your cough. We want to know if different things in your life make your cough worse. We will add to what's known about the app by collecting information from people with and without asthma. We will learn about other health factors or daily life that may affect your asthma. We are looking for people living in New Haven, with and without asthma. The study will last one year. We will collect information on coughing, steps, flights of stairs climbed, walking speed, and mobility. We will ask you to write down information on your daily life activities.

This text above is at a Flesch Reading Ease score: **76.4** and Flesch-Kincaid Grade Level: **5.9**. That means it is fairly easy to read and is written for 11- to 12-year-olds.

More Inclusive Content - Formatting for Ease of Reading

We want to know if where you live makes your asthma worse. We are from the University College of New Haven (UCNH) and will study a new phone app, called Achoo Microphone. The app will allow us to learn about your cough. We want to know if different things in your daily life make your cough worse.

Study Goals

- Collect information from people with and without asthma,
- Learn about other health factors or daily life that may affect your asthma,
- We are looking for volunteers:
 - Living in New Haven,
 - People with asthma,
 - People without asthma.
- The study will last one year,
- We will collect information on coughing, steps, flights of stairs climbed, walking speed, and mobility,
- We will ask you to write down information on your daily life activities.

