

Design an Inclusive Engagement Plan

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 and results in sustained engagement for full participation in the entirety of the clinical trial.

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

An engagement plan is essential throughout the clinical trial life cycle. 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.

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Clinical trial success is dependent on robust outcomes from **all populations that stand to benefit** from the drug or product under investigation. This means designing and implementing intentional strategies to identify and engage diverse populations coupled with inclusive measures to ensure all participants can fully participate.

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 using each of these tools.

Benefits of an Inclusive Engagement Plan

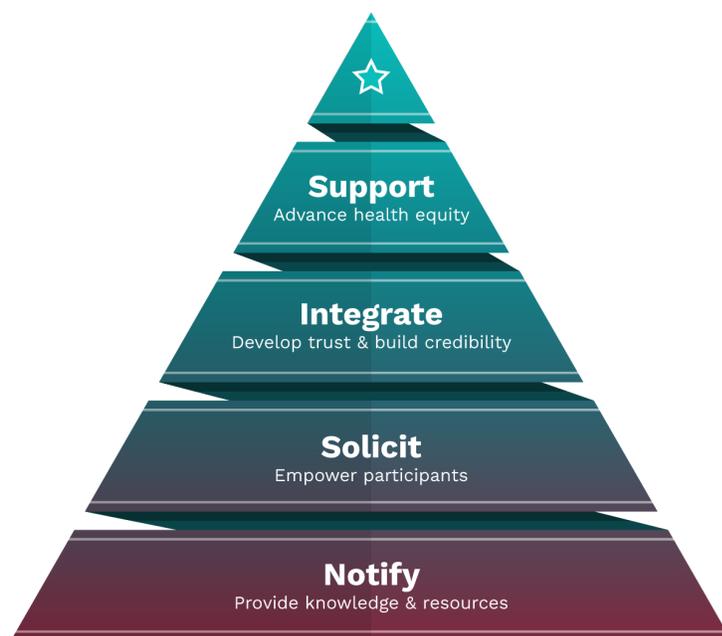
- Developing trust and building credibility for the sponsor, study product, and clinical trial team,
- Providing knowledge and resources to empower participants and giving them some influence in the process,
- Empowering participants to be more active with the clinical trial process; thereby leading to improved adherence, data collection, interpretation of results, and outputs,
- Advancing health equity with more complete and diverse data to inform health care, and with better educating and informing individuals as well as broader populations to participate in clinical trials.

Levels of Sponsor or Clinical Trial Team Engagement with Participants

Engagement can be undertaken in bulk or on an individualized basis, and can include strategies that range from passive to active. Below, we describe four levels of engagement that teams can use to evaluate current engagement efforts and upskill as relevant.

1. **Notify: Provide knowledge and resources**

The **lowest level** of engagement allows for participant activation and is similar to outreach, where **information is shared** with participants or communities. Information can be general, with **little to no interactions** with the



clinical trial team and can occur through multiple channels including digital campaigns (social media, websites, mass emails, online advertisements, newsletters), print media (advertisements, brochures), or in person (bulletin boards).

- a. It is **not sufficient** to provide information to participants: this information is not valuable **unless participants understand** the information and can act on it in a meaningful way. Select the modality that is best suited to the participant or community and use terminology that aligns with their culture, preferences, and literacy levels.
- b. It is **not sufficient** for participants **to see the information** and act on it independently. Consider health literacy training, tech literacy training, and providing answers in an understandable/actionable way.

2. **Solicit: Empower participants**

The second level of engagement allows for **some participant involvement**, where **participants** are **asked to provide information**. The collected information can be used to identify participant needs and assist with developing the engagement plan.

- a. Digital campaigns, digital companion apps, and virtual visits can be utilized to conduct focus groups or send out surveys.
- b. Mine RWD/RWE from datasets, including electronic health records or publicly available data such as the Census to learn more about the target participants.
- c. This will yield quantitative data; however, this does not allow for richness and adequate information on what the data means or how it is influenced by additional factors in the participant's life.
- d. This type of engagement may also be limited by many factors, including access, education, and socioeconomic status.

3. **Integrate: Develop trust and build credibility**

The third level of engagement **allows for interactions**; the participant is **invited to provide information** and given **a forum to elaborate and add meaning** to the information shared. Clinical trial teams now have the opportunity to go deeper into participant feedback to obtain a more comprehensive picture of how the participant can interact with the product.

- a. Start with notifying and soliciting, and then build on that information to get to integration.
- b. Reaching out to community groups and building partnerships is helpful for this level of engagement. See the guide "[Develop Community Partnerships to Build Trust](#)".
- c. This level of engagement includes using facilitated meetings, interactive focus groups, roundtable discussions, and open forums or town halls.



- d. Integrative engagement allows for quantitative and qualitative data collection, can be customized for specific demographics or health conditions, and can be short-term or long-term.

4. **Support: Advance health equity**

The fourth level of engagement is **multi-directional and mutually supportive**; it allows for **authentic partnerships**. **Participants** become **partners**. Supportive engagement is an **interactive process** with community partnerships to promote inclusivity throughout the clinical trial lifecycle.

- a. Engagement partners share decision making and learn from each other to innovate and strengthen outcomes.
- b. Along with a richer data collection, supportive engagement yields ideas for future work or identify additional opportunities to increase knowledge.
- c. Participants and/or community partners can be invited to serve on advisory boards or participate in other long-term activities.

Considerations for an Inclusive Engagement Plan

1. Identify specific **purpose of** and **goals for the engagement plan**, placing **inclusive recruitment** and **impactful use** at the center. Include **metrics for accountability** with diversifying your clinical trial.
2. Address the **composition** and **competencies** of the **clinical trial team** with respect to the race, ethnicity, age, sexual and gender identity, disability, or location, and language preferences of the groups you seek to recruit. If there are gaps in the team's understanding of inclusivity dimensions for specific populations, discuss how the gaps will be addressed. Possible solutions include **training, hiring, or partnering**. Members of the team should **reflect the diversity of the community**.
3. Meet participants where they are. **Digital access and literacy** are critical to full participation; therefore, make accommodations to **meet participants** at **different levels** and [provide resources to level-up](#) participants.
 - a. Do not expect participants to come to you. [Go into the communities](#); **identify partners** and other opportunities that will allow for engaging and recruiting diverse populations.
 - b. Develop materials that are **culturally respectful** and can **reach different audiences**.
 - i. Design outreach, engagement, and product materials at **different reading levels**.



- ii. Design outreach, engagement, and product materials for **different visual preferences** (for example, more images instead of text, or videos in addition to print materials).
 - iii. **Translate materials**, including informed consent, into the languages that reflect languages of your population.
 - c. Allow potential participants to express interest through **multiple mechanisms**: phone, email, online sign up, and/or QR code.
 - d. Provide support **customized to different audiences**. Ensure that members of the team can respond in participants' preferred language or mechanism.
4. **Provide support** so participants' have what they need to contribute fully.
- a. Recognize that participants are **adding value** to your work and be prepared to compensate them for their time and contributions.
 - b. Some participants may require **additional accommodations** such as child services, access outside of standard 9:00-5:00 workday, or transportation to participate.
 - c. Be prepared to offer **support** for **digital needs**
 - i. [Digital navigators](#) - work with community members to address needs throughout the digital inclusion process, including digital access and literacy.
 - d. Provide **accommodations** for **literacy** and **comprehension** needs. The **teach back** method is a good way to ensure participants understand the information you share.
 - e. Share the tools from the [DATAcc Inclusivity Workbook: Prepping End Users](#).
5. Consider these approaches when **meeting with the community or participants**.
- a. Use a **facilitative and culturally competent approach** with someone outside of the study team. A community partner can serve as a facilitator and help build the connection between participants and the team.
 - i. A facilitator will ask questions and create an atmosphere for open discussion and consensus-based decision making.
 - b. Design **curiosity questions** before designing the process (start with questions and allow participants to share their vision for getting to your outcomes):
 - i. Customize questions to the community or participants,
 - ii. Ask open-ended questions,



- iii. Maintain neutrality in sentence construction, for gender, race, age, sexual orientation, ethnicity, income, and different abilities,
 - iv. Be cognizant of cultural and literacy differences,
 - v. Be patient and respectful,
 - vi. Give all participants an opportunity to share and allow time for full discussions.
 - c. Use **different engagement tools** and **communication modalities** (e.g. phone, in person, email, mail, flyers) to get your message out and to receive feedback for planning:
 - i. Surveys
 - ii. Focus groups
 - iii. Workshops
 - d. **Be accommodating** to different thinking, learning, and feedback preferences:
 - i. Writing
 - ii. Speaking
 - iii. Drawing (visual displays)
 - iv. Observing
- 6. Develop and maintain a welcoming and **inclusive environment** throughout the clinical trial process:
 - a. Provide opportunities for **social interactions** and **relationship building** among participants,
 - b. Encourage different feedback mechanisms such as video, voice, photography, or writing,
 - c. Consider forming a **participant advisory board**,
 - d. Develop a process to share updates and data with end.
- 7. **Evaluate** the **engagement plan** throughout:
 - a. Build in milestones and deliverables with key performance indicators (KPIs) throughout the engagement plan,
 - b. Track participation by different groups,
 - c. Ask end participants for feedback on materials and interactions and other engagement activities,
 - d. Review these to ensure you are on track to meet your goals for



recruitment and retention,

- e. Adjust, with community partners as needed.
8. These **engagement strategies** should be **applied throughout** the clinical trial process and not only for enrollment. These steps will be **helpful for participant retention** and successful clinical trial **outcomes**.
9. Check out [The Resource Library: Inclusive Deployment](#) for additional recommendations, best practices, and templates.





References & Resources

1. [Assessing the Financial Value of Patient Engagement: A Quantitative Approach from CTTI's Patient Groups and Clinical Trials Project](#). Engagement activities with the potential to avoid protocol amendments and/or improve enrollment, adherence, and retention may add considerable financial value
2. [Clinical Trial Diversity: An Affective Trust Framework for Engaging & Recruiting Communities of Color](#). Acclinate's Affective Trust Framework establishes guiding principles and outlines practical recommendations for building trust, engaging communities, leveraging technology, and achieving health equity through inclusive research.
3. [CTTI Patient Group Engagement](#). A framework and resources to facilitate engagement between sponsors and patient advocacy groups throughout the clinical trial process.
4. [DATAcc: Workbook: Prepping End Users](#). Resources to support patients, participants, or communities to better understand the different aspects of digital health measurement products.
5. [Digital Equity Playbook](#). Resources and tools to better understand and serve underserved populations to promote digital equity.
6. [Digital Navigators](#). The Digital Navigator services model is a solution to address both digital access as well as learning and upskilling, and at scale.
7. [Digital Navigators Toolkit](#). Details on the digital navigator model and resources to use.
8. [Diversity, Inclusion, and Equity in Clinical Research](#). This toolkit provides general information and practical resources (logic models, checklists) to develop plans for more diverse representation in clinical research.
9. [How NIH Uses Community Health Partnership for Participant Engagement](#). Through the *All of Us* Research Program, NIH turned to community partnerships to establish trust with underserved communities to drive diversity and patient engagement.
10. [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.
11. [Improving Representation in Clinical Trials and Research](#). Underrepresentation is compounding health disparities, with serious consequences for underrepresented groups and for the nation.
12. [Increasing Black Participation in Metastatic Breast Cancer Clinical Trials](#). The Black Experience of Clinical Trials and Opportunities for Meaningful Engagement project aims to drive change by better understanding barriers to clinical trial participation for Black patients with metastatic breast cancer and identifying actions to increase participation.



13. [Innovation in Large-Scale Research Programs: Elevating Research Participants to Governance Roles Through the All of Us Research](#). Researchers co-learn with diverse community participants and gain valuable feedback salient to and informed by members of marginalized communities.
14. [Patient-Centered Outcomes Research Institute: Engagement Resources](#). Evidence-based best practices and tools for every step in the patient engagement process from building research teams to developing engagement plans and data analysis.
15. [Patient Engagement Guide for Sponsors and Contract Research Organizations \(CROs\)](#). This provides the business case and resources for patient engagement, specifically with clinical trials.
16. [Patient Engagement Methods Tool](#). This is a free, interactive online tool to help plan engagement activities for patients and communities.

