DIVERSITY, EQUITY, & INCLUSION in Digitized Clinical Trials

DIGITAL MEDICINE SOCIETY

Empower Through eConsent: Key Considerations

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 participant 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 awareness for participants on clinical trial participation value and process.

Ethical Considerations

The informed consent process and document are critical for explaining the clinical trial and for full participation. Better informed participants will lead to complete data collection and more data for interpreting your safety and efficacy results. These key considerations should be used as a guide, along with Federal guidelines for designing the informed consent document.

Equity and inclusivity require that you **ensure all participants can participate fully**. This 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.

Several digital tools can be utilized to create an empowering experience, these include eConsents, 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.

Empower Participants For Enrollment And Retention Through The Consenting Process

Transparency and clarity are important for empowering participants. This includes adequately informing participants so they can fully comprehend what is required for their participation in the clinical trial.

1. Start with an interactive eConsent to keep participants engaged and to increase comprehension:

   a. Use on demand videos with captioning to explain text heavy sections, and to allow for accessibility.
   b. Use pop-up information windows to explain terms and provide definitions and examples.
   c. Break up the content into smaller, more manageable sections.
   d. Use hyperlinks to allow participants to refer back to different sections.
   e. Use imagery to improve comprehension and to break up text heavy sections.
   f. Provide short quizzes at the end of each section to confirm participants comprehension before moving to the next section.
   g. Make parts of the document shareable so participants can include family or caregivers in this process.

2. Use plain language to meet participants at different literacy levels:

   a. Documents should be clearly formatted for reading ease and written at lower than an 8th grade reading level.
   b. Use short paragraphs and short words.
   c. Scripts and dialogue for videos should be clear and simple.
   d. Use people first and gender inclusive language.
   e. See Inclusive Communications Guide.

3. Be culturally respectful throughout the consenting process to build

credibility and develop a trusted relationship:

a. Provide the eConsent in multiple languages; validate translations with a native speaker.
b. When using videos and other imagery:
    i. include representation from diverse populations,
    ii. be cognizant of stereotypes and misrepresentations,
    iii. be authentic with the content of the video (e.g. characters or images should not be obviously happy or joyful when explaining a disease).
c. Provide video captioning in multiple languages; validate translations with a native speaker.

4. Include details specific to the use of digital tools or products:

a. Reason for using this product and how using it is applicable and beneficial to their health and life (emphasize value to the participant).
b. If the digital products will need access to other phone apps (camera).
c. Details on how to use the digital product, in simple, easy-to-follow steps.
d. Additional required products or services to participate in the trial (smartphone, broadband, etc.).
e. Types of data that will be collected (GPS, personal identifiable information).
f. How the data will be used (to manage health conditions, to collect data, to increase knowledge).
g. If additional costs are associated with participating in the clinical trial (buying an app, or membership to an app service).
h. Parties who will have access to the data.
i. Security measures in place to protect data and privacy.
j. If the participant can have access to the data and at what level (individual, aggregated).
k. Any additional information about the participant that will be collected as they participate in the trial.
l. Any potential harm associated with participating in the study, including any negative attention for participating, loss of privacy, or incurred costs.
m. Any other benefits of participating.
n. If the participant has to agree to all conditions (data use/sharing, functional options, etc) before trial start.
o. If the participant can choose which digital components to use.

5. Allow for open communications:

a. Provide details on how the participant can contact you with any questions.
b. Provide details on how you will contact the participant and share updates

on the clinical trial and/or digital health product.

6. Use the following resources to ensure completeness and inclusivity:

   a. The Elements of Informed Consent
   b. Digital Health Checklist for Researchers

7. When reviewing the consent document with the participant, consider including a family or friend to ensure the user adequately understands the additional requirements of participation (e.g. comfortable using the digital health product, data uploads, etc.)

   a. Use the CTTI Informed Consent Discussion Tool

References & Resources

1. 7 ways eConsent can help health researchers achieve better participant engagement. Tools like eConsent provides organizations with an efficient and streamlined way to garner consent from study participants.

2. Applying a Digital Health Checklist and Readability Tools to Improve Informed Consent for Digital Health Research. This paper describes a methodology that researchers can apply when developing consent communication for digital health research.

3. CTTI Informed Consent Discussion Tool. A tool to use as a checklist when developing and administering an informed consent.

4. Digital Health Checklist for Researchers. The DHC can be useful to technology developers, ethics boards, clinical personnel, and people considering participation in a digital health study

5. eConsent Done Right: A Powerful Tool to Build Trust and Diversity in Research . Recommendations on how to improve the eConsent process.

6. eConsent For Complex Clinical Trials. Sponsors can use eConsent platforms to deliver highly engaging and easy-to-audit consent processes that cut time and cost while creating a seamless user experience.

7. The Elements of Informed Consent. A toolkit for developing and administering informed consent for diverse audiences, and for using digital technologies.