

Hire a Digital Clinical Trials Navigator

What should I do?

Set clinical trial sites up for success and alignment with your goals for diversity, equity, and inclusion. Clinical trial sites and staff need training and support similar to participants, especially as you introduce digital tools into your trial.

Why should I do it?

- Reduced burdens for participants and clinical trial teams by streamlining processes.
- Build trust and transparency, and strengthen relationships between Sponsors and clinical trial teams.
- Increased compliance and participant adherence.
- Improved outcomes with more robust data collection.
- Increased and improved patient engagement and retention.
- Increased access and awareness for participants to clinical trial participation.
- Increased awareness for participants on clinical trial participation value and process.

Ethical Considerations

Support for clinical site teams and participants will be critical for executing strategies for digitizing clinical trials and for improving diversity, equity, and inclusion. It is imperative that clinical sites and participants have adequate information, training, and support. The recommendations for a Digital Clinical Trials Navigator should be used as a starting point; customize and enhance as needed to help support your clinical teams and participants.

We recommend adding a **support role** to your trial teams, a Digital Clinical Trial Navigator (DCTN). This role can come from the Sponsor, Contract Research Organization (CRO), or clinical site level. The responsibilities here can also be rolled into a clinical research associate or coordinator role. The DCTN will focus on **implementing** your **strategies to digitize** your **clinical trial** with a focus on inclusivity. This role will be instrumental for a **person-centric approach** and in ensuring **clinical trial compliance, retention**, 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 for this role; these include digital companion apps, 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.

Role Description

The DCTN **serves as a bridge between the clinical trial designers** (Sponsors, CROs, sites) **and the participant**, to provide training and support with the use of digital tools. The DCTN assesses participants' access to and basic knowledge on using digital technologies, provides training on basic digital skills and on using digital products associated with the clinical trial. While much of this work can be completed with the use of a digital companion app, on demand videos, and virtual visits, some on site visits may be required to help participants get set-up. The DCTN will also be available throughout the clinical trial life cycle to **provide continuous support to participants and other site staff** with the use of the digital tools.

Responsibilities

1. Once a participant has selected to join the clinical trial, meet with them to assess the level of assistance needed to enroll in the trial (e.g. assistance for eConsent).
2. Assist clinical research coordinator with enrolling the participant.
3. Once a participant is enrolled, prior to the start of clinical trial activities, meet with the participant to conduct a full assessment of their digital readiness level, including internet access at home, level of comfort with digital health technologies.
4. With the clinical research coordinator/Principal Investigator/other clinical team members, develop a customized plan for training and supporting each participant. Include different levels for each participant, such as independent, facilitation needed, assistance needed, to prioritize and ensure equity among participants.



5. Develop a process to track and evaluate participant's progress and comfort with the digital tools, at some regular interval.
6. Develop a plan to ensure participants receive continuous support throughout the clinical trial life cycle, as needed.
7. Collect qualitative data on participants comfort and proficiency levels and use of the digital tools, to inform data analyses.
8. Assess the other site team's digital readiness with the digital tools specific to this clinical trial.
9. Provide training and support to the site team as needed.
10. Track and evaluate the site team's proficiency and effectiveness with the digital tools.

Qualifications

1. Ability to use digital technologies, and a general excitement to learn about digital health technologies.
2. Ability to quickly learn and master new technologies.
3. Ability and patience to explain and train others on complex concepts and processes.
4. Ability to think creatively and problem solve.
5. High level of emotional intelligence and cultural awareness.
6. Excellent communication skills.
7. Ability to work independently and in a team environment.





References & Resources

1. [Digital Navigator Baseline Job Description](#). Digital Navigators model can be adapted to the capacity you have available, be it newly dedicated full-time employees, cross-trained staff, or volunteers.
2. [Overcoming Barriers to Clinical Trial Enrollment](#). Research has increasingly focused on overcoming barriers to clinical trial enrollment; one solution is the use of patient navigators to help enhance clinical trial recruitment, enrollment, and retention.
3. [The Digital Navigator Playbook](#). This comprehensive guide details the steps and considerations as programs and systems setup or improve their Digital Navigator services.