

Implement Digitized Clinical Trials



Digital Recruitment & Retention

Digital tools to streamline all steps in the trial process that require engagement of participants and clinical staff



Digital Health Data Collection

Digital tools to enhance and expand data collection and integration with additional sources



Digital Analytics

Digital tools to integrate, analyze, and report data and findings from clinical trials



Digital Readiness

Strategic planning upstream to designing and throughout the clinical trial cycle



Digital Readiness

Description: Digital readiness is the **state of ease with adopting and implementing digital tools** into the clinical trial lifecycle. Strategic planning and designing are needed prior to implementing a digitized clinical trial, and checks and balances are needed throughout the lifecycle of the trial to maintain digital readiness.

Digital tools offer the opportunity to **streamline clinical trial processes** and **increase workflow efficiencies** while decreasing costs and driving a more person-centric approach. A trial can be digital regardless of whether trial activities are conducted at a clinical research site (traditional clinical trial) or away from the research site (decentralized clinical trial).

Implementation: To **maintain a state of digital readiness**, clinical trial sponsors, clinical research and decentralized clinical trial organizations, and clinical research sites should develop a **digital readiness plan**. The digital readiness plan should include information on how to identify which digital tools are best suited to each step of the clinical trial and information on training and supporting clinical site teams with using the digital tools. Digital tools also present the opportunity to advance health equity. Therefore, the digital readiness plan should also include details on how to **be equitable** and **inclusive** when digital tools are integrated.



Digital Recruitment & Retention

Description: Digital recruitment and retention is the use of **digital tools** to **optimize** and **streamline** all steps in the clinical trial process that require **engagement of participants** and **clinical staff** to collect data.

Strategies for digital recruitment and retention should be included in all steps of a traditional clinical trial: study design and protocol development, site selection and initiation, and participant outreach, engagement, recruitment, enrollment, and retention.

Implementation: Digital recruitment and retention provides **opportunities to address challenges** plaguing the clinical trials industry and participants, including lack of awareness and access to trials, low recruitment and retention rates, missed enrollment milestones, incomplete data collection, and extended timelines.

The following digital tools can be applied to digital recruitment and retention

- Artificial Intelligence/Machine Learning (AI/ML)
- Real-World Data/Real-World Evidence (RWD/RWE)
- Social media/Digital marketing
- Electronic consenting (eConsent)
- On-demand videos



- Virtual visits (telehealth).

See the “[Elements of a Diverse, Equitable, and Inclusive Digital Clinical Trial](#)” for details on using digital tools for digital recruitment and retention.



Digital Health Data Collection

Description: Digital health data collection is the use of **digital tools** to **enhance data collection** and **expand** on the **types of data** and information collected. The traditional clinical trial steps of clinical data management and trial monitoring are included in digital health data collection.

Digital tools, such as digital clinical measures (including remote patient monitoring) and digital non-clinical measures allow for more efficient and real-time data collections and better integration with existing data sources. Additional data sources collected with digital tools include patient-generated health data, patient-reported outcomes, ecological momentary assessments, digital biomarkers, and wearable and mobile sensing measures.

Implementation: Digital health data collection can **address challenges** associated with missed enrollment milestones, incomplete data collection, static assessments, patient recall, patient adherence, and extended timelines.

See the “[Elements of a Diverse, Equitable, and Inclusive Digital Clinical Trial](#)” for details on using digital tools for digital health data collection.



Digital Analytics

Description: Digital analytics is the use of **digital tools** to **integrate, analyze, and report** data collected for clinical trials protocols. The traditional clinical trial steps of statistical analyses and report-writing are included in digital analytics.

Implementation: Digital analytics relies on digital tools such as AI/ML, RWD/RWE, digital companion app, and digital platforms. Digital analytics will **address challenges** associated with incomplete data collection, static assessments, patient recall, and extended timelines.

See the “[Elements of a Diverse, Equitable, and Inclusive Digital Clinical Trial](#)” for details on using digital tools for digital analytics.



References & Resources

1. [Digitizing clinical trials](#). The concept of a “digital clinical trial” involves leveraging digital technology to improve participant access, engagement, trial-related measurements, and/or interventions, enable concealed randomized intervention allocation, and has the potential to transform clinical trials and to lower their cost.
2. [Digital health: An opportunity to advance health equity](#). Digital health solutions have the potential to make healthcare more equitable. Here’s how innovators can deliver on that promise.
3. [Digital Health Technologies in Trials: A Keyword-based Analysis](#). Using a pre-existing set of more than one thousand keywords to search ClinicalTrials.gov, this analysis attempts to quantify the number of trials using digital health technologies. The results of this search suggest a steady increase in the number of trials using DHTs.
4. [Digitalization at scale: Delivering on the promise of science](#). A new bar has been set and companies are now willing to move beyond convention to solve the toughest challenges and stand to reap the biggest benefits.
5. [Using digital technologies in clinical trials: Current and future applications](#). Much of the published research demonstrates how digital approaches can improve the design and implementation of clinical trials.

