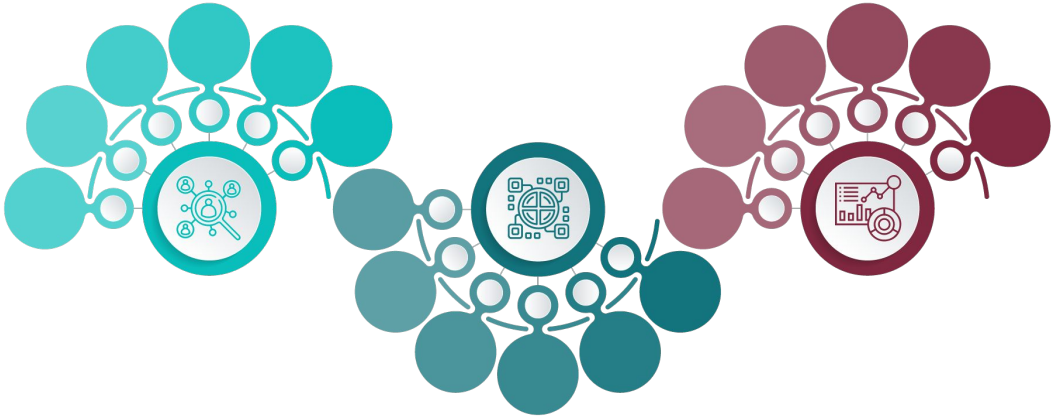
DIVERSITY,
EQUITY, &
INCLUSION
in Digitized Clinical Trials

DIGITAL MEDICINE SOCIETY

Elements of a Diverse, Equitable, & Inclusive Digitized Clinical Trial



Intro

DE&I = Diverse, Equitable, & Inclusive

Digital tools have the potential to **transform healthcare** and **clinical trials** by **increasing efficiencies** and **reducing costs**. With this comes the opportunity to **advance health equity**. While the digital toolbox is quickly growing and evolving, there are 10 digital tools that can be used now to address many of the challenges facing the clinical trials industry and help advance diversity, equity, and inclusion. The Elements of a Diverse, Equitable, & Inclusive Digital Clinical Trial resource highlights the application of digital tools to specific clinical trial processes. See "Elements of a Digitized Clinical Trial - Expanded" for additional examples of each digital tool's application in the clinical trial process.

DIGITAL TOOLS LEGEND

AI/ML Artificial Intelligence/Machine Learning

Clin Digital Clinical Measures

Comp Digital Companion App

eCon eConsent

Non Clin Digital Non-Clinical Measures

RWD/RWE Real World Data/Evidence

Social Social Media/Digital Marketing

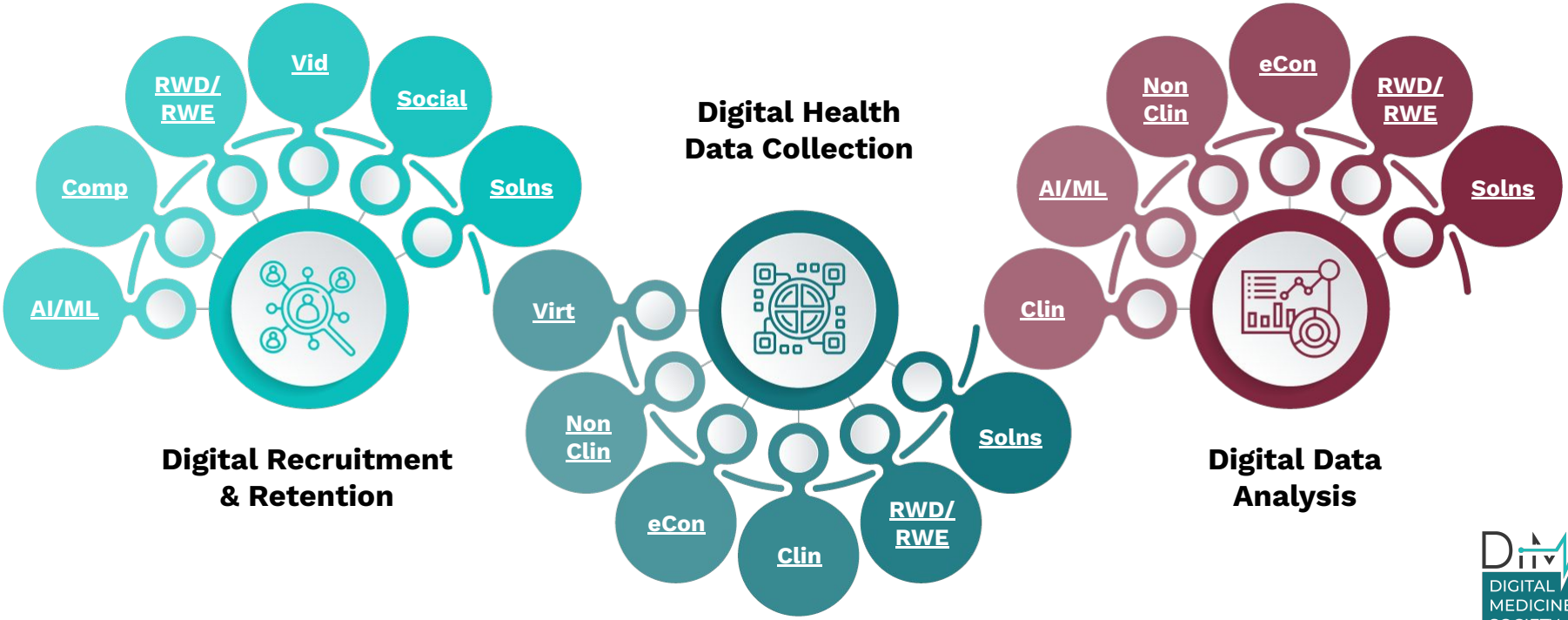
Solns Digital Platforms/Solutions for Efficiencies

Vid On-Demand Videos

Virt Virtual Visits (Telehealth)

Digital Tools Support DE&I at each clinical trial step

Click to jump to a digital tool



Tool: Artificial Intelligence/Machine Learning (AI/ML)

AI is the general ability of computers to imitate human-like thinking to perform tasks in real-world environments through processing of mathematical algorithms and statistical methodologies. ML refers to the specific technologies and algorithms that allow computational systems to identify patterns, make decisions, and evolve through data processing.

Opportunities +

- Expand sources to identify and engage more participants
- Go beyond/supplement passive recruitment efforts such as advertising
- Reach participants at multiple sites concurrently
- Increase participants' access to trials
- Increase trial sponsors and sites' access to participants
- Avoid delays from participants limited experience and knowledge of clinical research opportunities or by systemic biases that may exclude underrepresented populations

How to use it

- Use for recruitment and enrollment of participants
- Identify populations most relevant to the health condition of interest for engagement and enrollment
- Examine large amounts of data to detect patient subgroups that may benefit from this trial
- Conduct participant matching - match specific participants and trials that are recruiting through integration with EHRs, medical devices, and wearables, and recommend these matches to doctors and potential participants
- Know where data limitations exists and identify methods to minimize bias

Examples

AI identified those who received ECGs as part of routine care from a total of 22,641 adults (N = 11,573 intervention; N = 11,068 control) to include in the study.

Reference: Artificial intelligence–enabled electrocardiograms for identification of patients with low ejection fraction: a pragmatic, randomized clinical trial

Additional References: Bias in AI: What it is, Types, Examples & 6 Ways to Fix it in 2023; A Comprehensive Look at the Use of AI for Clinical Trials. Disrupting Clinical Development with Artificial Intelligence

Tool: Digital Companion App

A digital companion app is a mobile app that allows participants to input, track, and store information about a disease, condition, or other factor related to study participation. Through the use of smartphones and a digital companion app, participants are no longer bound by time and location in order to learn about and participate in clinical studies.

Opportunities +

- Truly meet participants where they are
- Reach participants at multiple sites concurrently
- Empower and educate participants on research opportunities
- Expand sources to identify and engage more participants
- Increase participants access to trials
- Increase trial sponsors and sites' access to participants
- Avoid delays from participants limited experience and knowledge of clinical research opportunities or by systemic biases excluded underrepresented populations

How to use it

- Use for recruitment and enrollment of participants
- Leverage "direct-to-participant" engagement strategies
- Expand the catchment area to identify more diverse participants, from wider geographic radius of the study site
- Customize engagement strategies
- Streamline workflows for evaluating participant eligibility
- Accelerate timelines for participant enrollment
- Know which participant populations are comfortable and have access to digital applications
- Make accommodations for others

Examples

Within 3 months, the study enrolled 30,529 individuals, with representation from every state in the United States.

Reference: Wearable sensor data and self-reported symptoms for COVID-19 detection
Additional References: A New Approach to Enhancing Engagement in eHealth Apps; Healthcare Apps Promise Powerful Outcomes — If Patients Use Them

Tool: Real-World Data/Real-World Evidence (RWD/RWE)

RWD is data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. RWE is the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD. RWD/RWE becomes more powerful when combined with AI/ML methodologies.

Opportunities +

- Reach participants at multiple sites concurrently
- Expand sources to identify and engage more participants
- Increase participants' access to trials
- Increase trial sponsors and sites' access to participants
- Streamline workflows for participant engagement, recruitment, and retention
- Identify avenues to empower and educate participants on research opportunities

How to use it

- Use with recruiting sites to participate in the study and to set up study initiation
- Identify communities in which to engage based on the therapy being studied
- Learn about community culture and utilize this information to better serve those populations
- Learn about clinical site process and successes to optimize recruitment and retention efforts
- Know where there are limitations with the datasets and supplement with multiple sources

Examples

RWD/RWE was used to identify 121 primary care teams from 45 clinics and hospitals.

Reference: Artificial intelligence–enabled electrocardiograms for identification of patients with low ejection fraction: a pragmatic, randomized clinical trial.

Additional References: 9 Ways Real-World Evidence is Changing Healthcare.

Tool: On-Demand Videos

On-demand videos provide content that is created for a wide audience and easily accessible through the use of recorded live action or animation, including educational materials on clinical trials and information that is specific to medications and therapies, or specific healthcare processes.

Opportunities +

- Reach multiple participants simultaneously
- Reach participants at different levels (language, accessibility, cognition)
- Increase accessibility and meeting participants where they are
- Empower and educate participants with on demand access to study materials
- Streamline workflows for ongoing participant engagement and assistance
- Begin to build trust and credibility by providing support to participants

How to use it

- Use with participant recruitment and enrollment, recruiting sites to participate in the study, initiating the study, and throughout study design and protocol development
- Provide convenience and streamline workflows for participant outreach, engagement, and enrollment
- Educate and inform participants, including during the consenting process
- Train participants and clinical staff
- Share updates with participants
- Know which participant populations are comfortable and have access to video capabilities
- Make accommodations for others

Examples

Video was used to consent patients at 67 sites across the country. Sites were able to begin engagement with patients much earlier and more African-American, elderly, and patients without a college degree were recruited.

Reference: Video informed consent leads to faster and more diverse patient enrollment.

Additional References: Use of Video Education Interventions to Increase Racial and Ethnic Diversity in Cancer Clinical Trials: A Systematic Review.

Tool: Social Media/Digital Marketing

Social media/digital marketing utilizes the Internet and online-based digital technologies such as desktop computers and mobile devices (phones, tablets) to promote clinical trials through channels, such as email marketing, paid social media marketing, video hosting tools, or social media.

Opportunities +

- Reach participants at multiple sites concurrently
- Increase accessibility and meeting participants where they are
- Expand opportunities to identify and engage more participants
- Empower and educate participants on research opportunities
- Increase participants' access to trials
- Increase trial sponsors and sites. access to participants
- Streamline workflows and reduce time and costs for participant engagement, recruitment, and retention
- Begin to build trust and credibility

How to use it

- Use with participant recruitment and enrollment, recruiting sites to participate in the study, initiating the study, and throughout study design and protocol development
- Identify which social media platforms are frequented by your target participants
- Customize engagement materials
- Learn about community culture and utilize this information to better serve those populations
- Know which participant populations are comfortable and have access to social media/digital marketing channels
- Identify alternative mechanisms to reach those without any or limited access

Examples

Social media can increase clinical trial participation, by up to 49% and reduce costs.

Reference: The Role of Social Media in Enhancing Clinical Trial Recruitment: Scoping Review.

Additional References: What is the difference between Digital Marketing vs. Traditional Marketing?

Tool: Digital Platforms/Solutions for Efficiencies

Digital platforms/solutions for efficiencies are technology-based business models, systems, or products that are utilized in clinical trials to increase efficiencies, such participant engagement, data collection and administrative management.

Opportunities +

- Increase accessibility and meeting participants where they are
- Reach participants at multiple sites concurrently
- Increase participants access to trials
- Increase trial sponsors and sites' access to participants
- Streamline workflows for participant engagement, recruitment, and retention
- Reduce participant and site burdens, reduce costs
- Improve reputation of clinical trials industry

How to use it

- Use with participant recruitment and enrollment, recruiting sites to participate in the study, initiating the study, and throughout study design and protocol development
- Identify which digital platform or solutions suit your needs
- Multiple platforms may be needed
- Customize engagement and enrollment experiences
- Streamline workflows for participant outreach, engagement, recruitment, and retention
- Know which participant populations are comfortable and have access to which digital platforms/solutions
- Identify alternative mechanisms to reach those who do not have access or to support those who need additional support

Examples

Digital health platforms enable clinical research in diverse populations and remove logistic and economic burdens on patients for clinical trial participation.

Reference: Enabling diversity in clinical research through a digital health platform.

Additional References: BC Platforms to Enable Longitudinal RWD and Genomics Access for Drug Development in Africa.

Tool: Virtual Visits (Telehealth)

Virtual visits (telehealth) allow for the use of digital information and communication technologies, such as computers and mobile devices, to access health care services remotely and manage care. Telehealth can also be used in clinical trials to conduct participant visits remotely.

Opportunities +

- More access to diverse populations
- Reduce sample sizes, increase study power, and reduce costs with richer data for each participant
- Reach and serve participants at multiple sites concurrently
- Increase participants' access to trials
- Increase trial sponsors and sites' access to participants
- Create more accessible, affordable, timely, and scalable participant-centric research
- Avoid delays by reducing burdens on participants and clinical team

How to use it

- Use for trial monitoring and clinical data management
- Collect qualitative data to supplement quantitative data collections
- Monitor participation and provide customized support for participants
- Streamline workflows for participants and clinical staff

Examples

Telehealth measures allowed for a personalized and scalable approach for patients.

Reference: Digital Health Coaching for Type 2 Diabetes: Randomized Controlled Trial of Healthy at Home

Tool: Digital Non-Clinical Measures

Digital non-clinical measures are patient-generated data that are collected with a sensor, but not specific to the health outcomes or physiological characteristics of an individual's health or wellness.

Opportunities +

- Create more accessible, affordable, timely, and scalable participant-centric research
- Reduce burdens on participants and clinical staff
- Collect additional and more relevant measures
- Increase retention
- Streamline workflows
- Improve participant experience and build trust
- Inform disease progression by identifying deteriorating patients who require advanced therapies
- Reduce likelihood of trial disruption (e.g., prevent withdrawal, non-adherence, inconclusive study)

How to use it

- Use for trial monitoring and clinical data management
- Track participant engagement/adherence in real-time to learn which participants may drop out/be lost to follow-up
- Inform study teams of the need to introduce processes to re-engage participants
- Track adverse events in real-time tracking or other measures that may lead to an adverse event
- Train clinical teams on the type of non clinical measures being collected

Examples

Digital technologies may reduce patient burden, improve drug adherence, provide a means of more closely engaging with the patient, and enable higher quality, faster, and more frequent data collection.

Reference: Digitally Enabled, Patient-Centric Clinical Trials: Shifting the Drug Development Paradigm

Tool: eConsent

Electronic consent, or eConsent, covers all the same information that you would in a traditional informed consent process and form, but it does so electronically. eConsent can be completed on a computer, tablet, or phone. It can be administered by study staff or completed independently by the participant at the site or remotely.

Opportunities +

- Create customized, accessible, and scalable participant-centric research
- Reduce burdens on participants and clinical staff
- Collect additional information on participant comfort and comprehension
- Improve engagement for increased retention
- Streamline workflows and reduce likelihood of trial disruption
- Improve participant experience and build trust
- Increase access to diverse participants, for sites and sponsors
- Increase site and sponsor knowledge of diverse participants

How to use it

- Use for clinical data management in addition to enrollment
- Collect metadata from the eConsent process
- Evaluate metadata for clues on how best to maintain participant engagement
- Design a plan to provide assistance to specific participants
- Modify study activities seamlessly and more efficiently
- Learn which participants prefer non-electronic interactions and make necessary arrangements to accommodate them

Examples

eConsent records patient interactions with the system, quantitative insights on site activities, study-specific site enrollment, and performance metrics.

Reference: eConsent: Using Metadata to Support Study Oversight and Enhance Informed Consent

Additional References: Why eConsent Primes Patients and Studies for Success

Tool: Digital Clinical Measures

Clinical measures are health outcomes or physiological characteristics of an individual's health, wellness, or condition that are collected digitally with a sensor.

Opportunities +

- Collect additional information for deeper knowledge on participant lived experiences
- Create more accessible, affordable, timely, and scalable participant-centric research
- Reduce burdens on participants and clinical staff
- Improve participant experience and build trust
- Identify disease progression by identifying deteriorating patients who require advanced therapies
- Reduce site visits and reduce likelihood of trial disruption (e.g., prevent withdrawal, non-adherence, inconclusive study)

How to use it

- Use for trial monitoring and clinical data management
- Collect continuous measures in real time without the need for clinical site visits
- Collect and evaluate metadata to improve participant's experience
- Track adverse events in real-time tracking or other measures that may lead to an adverse event
- Ensure participants have sufficient resources to fully use digital measure products, including access to internet, knowledge with using digital tools, and continuous support

Examples

Digital clinical measures (RPM) allows for more patient participation and better satisfaction, and ensures that high quality data is collected throughout the trial.

Reference: The Use of Telemedicine in Cancer Clinical Trials: Connect-Patient-to-Doctor Prospective Study

Tool: Real-World Data/Real-World Evidence (RWD/RWE)

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Opportunities +

- Collect additional information for deeper knowledge on participant lived experiences
- Create more accessible, affordable, timely, and scalable participant-centric research
- Reduce burdens on participants and clinical staff
- Use collected data to improve participant experience and build trust
- Create workflow efficiencies by streamlining data collections and using RWD to supplement
- Reduce sample sizes, increase study power, and reduce costs with richer data for each participant

How to use it

- Use for trial monitoring and clinical data management
- Identify additional information that may impact the data collected for this trial from EHR or claims databases
- Collect and evaluate metadata to improve participant's experience or inform trial processes
- Evaluate public datasets or other sources to get more information on participants lived experiences

Examples

RWD/RWE can provide information on the long-term safety, pertaining to rare events, and effectiveness of drugs in large heterogeneous populations, as well as information on utilization patterns and health and economic outcomes.

Reference: Interpretation and Impact of Real-World Clinical Data for the Practicing Clinician

Additional References: The Expanding Role of Real-World Evidence Trials in Health Care Decision Making

Tool: Digital Platforms/Solutions for Efficiencies

Digital platforms/solutions for efficiencies are technology based business models, systems, or products that are utilized in clinical trials to increase efficiencies, such participant engagement, data collection and administrative management.

Opportunities +

- Create more accessible, affordable, timely, and scalable participant-centric research
- Reduce burdens on participants and clinical staff
- Collect additional information for deeper knowledge on participant lived experiences
- Increase retention
- Improve participant experience and build trust by using their time more efficiently
- More access to diverse populations
- Reach participants at multiple sites concurrently
- Increase participants' access to trials
- Increase trial sponsors and sites' access to participants

How to use it

- Use for trial monitoring and clinical data management
- Help participants with completing study activities
- Supplement additional resources
- Track participation
- Customize use of digital platforms and solutions to reach participants where they are with the digital divide

Examples

This platform allowed clinical staff to assist participants with overcoming the digital divide and aided them in completing activities in Spanish.

Reference: Are Your Digital Tools an Unintended Barrier to Diversity in Research? How to Bridge the Technology Gap for Research Participants

Additional References: CATI – combat COVID isolation and engage health research participants

Tool: Digital Clinical Measures

Clinical measures are health outcomes or physiological characteristics of an individual's health, wellness, or condition that are collected digitally with a sensor.

Opportunities +

- Identify innovative therapies to advance health equities
- Increase opportunities to collect additional and more relevant measures
- Improve outcomes and increase likelihood of technical success
- Better inform go/no-go regulatory and reimbursement strategy and decisions
- Create more efficient post-market surveillance and inform future studies
- Increase opportunities to build trust and improve participant experience
- Improve participation and reputation of clinical trials industry

How to use it

- Use for statistical analyses and final reporting
- Identify secondary and tertiary outcomes with added depth to trial specific data
- Model newly-collected data against existing data for more complete analyses
- Identify measures that may inform future studies

Examples

Monitoring certain vitals and collecting richer data in real time help sponsors make smarter decisions about their clinical trials.

Reference: What The Fitbit Is Helping Pharma Learn About Patients

Tool: Artificial Intelligence/Machine Learning (AI/ML)

AI is the general ability of computers to imitate human-like thinking to perform tasks in real-world environments through processing of mathematical algorithms and statistical methodologies. ML refers to the specific technologies and algorithms that allow computational systems to identify patterns, make decisions, and evolve through data processing.

Opportunities +

- Increase opportunities to collect additional and more relevant measures
- Improve outcomes and increase likelihood of technical success
- Identify innovative therapies to advance health equities
- Increase opportunities to build trust and improve participant experience
- Better inform go/no-go regulatory, and reimbursement strategy and decisions
- Create more efficient post-market surveillance and inform future studies
- Improve participation and reputation of clinical trials industry

How to use it

- Use for statistical analysis and final reporting
- Model newly collected data against existing data for more complete analyses
- Identify secondary and tertiary outcomes with added depth to trial specific data

Examples

AI algorithms and machine-learning-based approaches are superior to traditional or conventional statistical methods for predicting cardiovascular events.

Reference: Applying Artificial Intelligence to Wearable Sensor Data to Diagnose and Predict Cardiovascular Disease: A Review

Tool: eConsent

Electronic consent, or eConsent, covers all the same information that you would in a traditional informed consent process and form, but it does so electronically. eConsent can be completed on a computer, tablet, or phone. It can be administered by study staff or completed independently by the participant at the site or remotely.

Opportunities +

- Create customized, accessible, and scalable participant-centric research
- Reduce burdens on participants and clinical staff.
- Collect additional information for deeper knowledge on participant lived experiences
- Improve engagement for increased retention
- Streamline workflows and reduce likelihood of trial disruption
- Improve participant experience and build trust
- Increase access to diverse participants, for sites and sponsors
- Increase site and sponsor knowledge of diverse participants

How to use it

- Use for statistical analysis and final reporting.
- Use metadata to collect additional insights which may be associated with study outcomes or can serve as secondary outcomes (e.g. preferred language).
- Review metadata of eConsent elements (e.g, time spent per screen, number of times accessed before completed) to streamline processes for future studies.

Examples

eConsent records patient interactions with the system, quantitative insights on site activities, study-specific site enrollment, and performance metrics.

Reference: eConsent: Using Metadata to Support Study Oversight and Enhance Informed Consent

Tool: Digital Clinical Measures

Clinical measures are health outcomes or physiological characteristics of an individual's health, wellness, or condition that are collected digitally with a sensor.

Opportunities +

- Improve outcomes and increase likelihood of trial success
- Identify innovative therapies to advance health equities
- Collect additional and more relevant measures
- Increase opportunities to build trust and improve participant experience
- Better inform go/no-go regulatory, and reimbursement strategy and decisions
- Create more efficient post-market surveillance with remote monitoring capabilities
- Improve participation and reputation of clinical trials industry

How to use it

- Use for statistical analysis and final reporting
- Use additional information on participant adherence to more comprehensively analyze treatment effectiveness
- Add depth to trial specific data analysis, supplement quantitative metrics

Examples

Patients were monitored for date, time and GPS location during medication use; this allowed support for improved asthma outcomes.

Reference: Impact of a mobile health pilot study on asthma rescue inhaler use, control and self-management

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Opportunities +

- Better inform go/no-go regulatory, and reimbursement strategy and decisions
- Identify innovative therapies to advance health equities
- Improve outcomes and increase likelihood of technical success
- Increase opportunities to collect additional and more relevant measures
- Increase opportunities to build trust and improve participant experience
- Create more efficient post-market surveillance and inform future studies
- Improve participation and reputation of clinical trials industry

How to use it

- Use for statistical analysis and final reporting
- Use additional information on participant environment to more comprehensively analyze treatment effectiveness
- Add rigor to trial specific data analysis, supplement quantitative metrics

Examples

Examining public data sources allow for a wider catchment area and provide more information beyond static measurements.

Reference: Dynamic Public Health Surveillance to Track and Mitigate the US COVID-19 Epidemic: Longitudinal Trend Analysis Study

Additional References: Trial designs using real-world data: The changing landscape of the regulatory approval process

Tool: Digital Platforms/Solutions for Efficiencies

Digital platforms/solutions for efficiencies are technology based business models, systems, or products that are utilized in clinical trials to increase efficiencies, such participant engagement, data collection and administrative management.

Opportunities +

- Reduce likelihood of trial disruption
- Improve outcomes and increase likelihood of technical success
- Identify innovative therapies to advance health equities
- Increase opportunities to build trust and improve participant experience
- Better inform go/no-go regulatory, and reimbursement strategy and decisions
- Create more efficient post-market surveillance and inform future studies

How to use it

- Use for statistical analysis and final reporting, in addition to clinical data management
- Use the digital solution of blockchain to collect and make stored data imputable and permanent
- Ensure data provenance and integrity

Examples

Blockchain technology presents an opportunity to address some of the common threats to the integrity of data collected in clinical trials and ensure that the analysis of these data comply with prespecified plans.

Reference: Using Blockchain Technology to Manage Clinical Trials Data: A Proof-of-Concept Study

Additional References: Ensuring protocol compliance and data transparency in clinical trials using Blockchain smart contracts