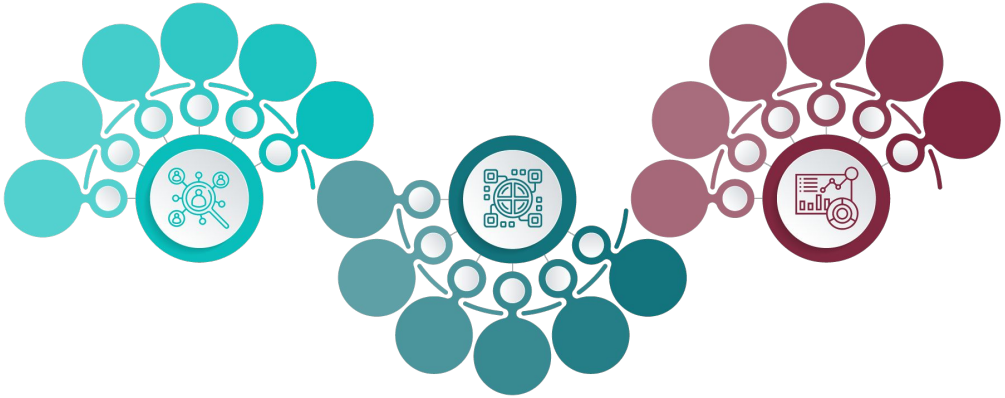
DIVERSITY,
EQUITY, &
INCLUSION
in Digitized Clinical Trials

DIGITAL MEDICINE SOCIETY

EXPANDED

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



Introduction

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 - Expanded resource provides examples of how each digital tool can be applied to each step in the clinical trial process.

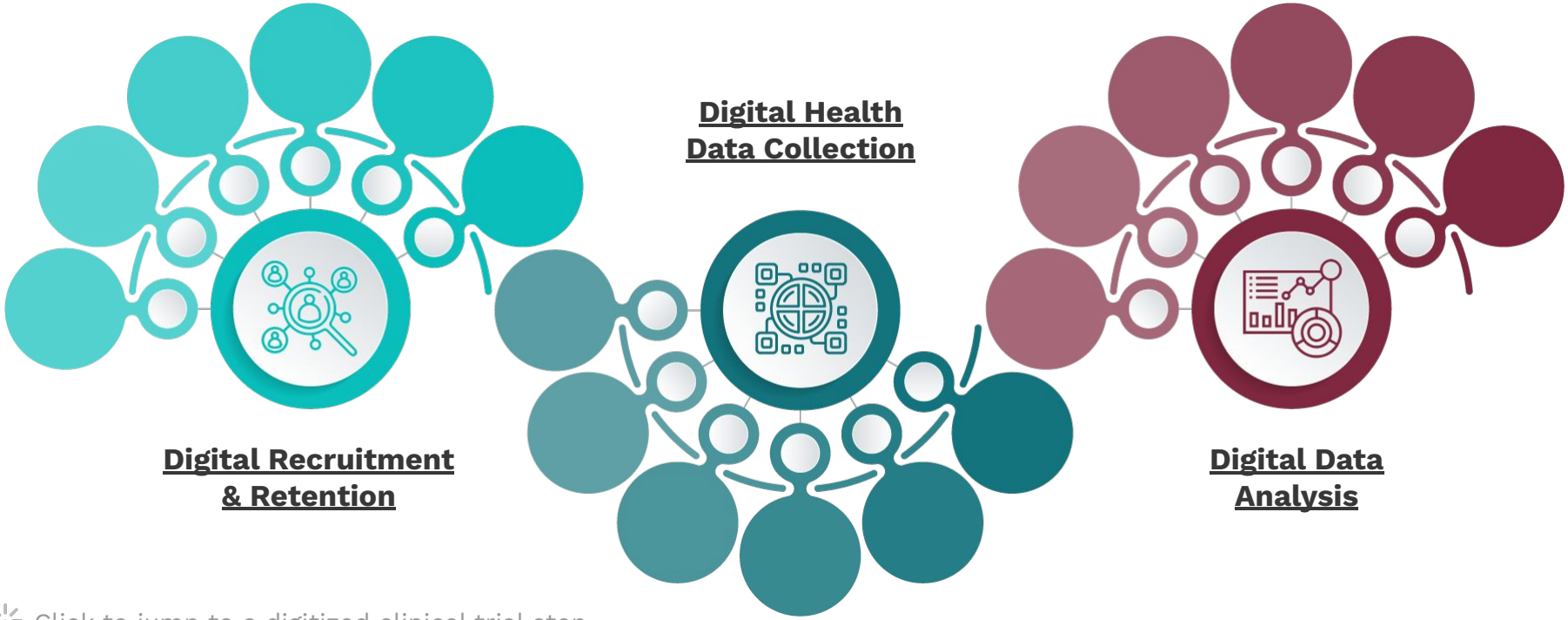
What should I do?

Use this resource to learn how each digital tool can be used in each step of the digitized clinical trial process. Identify which tools are best suited for addressing specific challenges facing health equity and clinical trials.

Why should I do it?

- Increase access and awareness for participants to clinical trials.
- Increase access of 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.
- Build trust working directly with diverse communities.
- Accelerate recruitment timelines with fewer participants needed for analysis, decreased time lost to participant screening, and streamline all processes for participants and clinical teams.
- Collect more relevant measures and non-clinical measures which can lead to improved outcomes and more robust data.

Digital Tools Support DE&I at each clinical trial step



Click to jump to a digitized clinical trial step

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.

Digital Tools:

- Artificial Intelligence/Machine Learning (AI/ML)
- Digital Clinical Measures
- Digital Companion App
- Digital Non-Clinical Measures
- Digital Platforms/Solutions for Efficiencies
- eConsent
- On-Demand Videos
- Real World Data/Real World Evidence (RWD/RWE)
- Social Media/Digital Marketing
- Virtual Visits (Telehealth)

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.
- Increase efficiencies by learning and adjusting processes based on collected data.
- Identify where data limitations exists and identify methods to minimize bias.
- Begin to build trust and serve participants better with increased knowledge on different populations or communities.

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

How to use it

- Use for site selection and study initiation.
- Assess workflow efficiency for specific clinical sites.
- Utilize this information to develop Standard Operating Procedures (SOPs) for recruitment and retention.
- Use machine learning and predictive analytics to maximize site performance.

Examples

Use AI to identify key drivers of enrollment, leading to the prediction of the most successful sites.

Reference: Follow the Data. Data-driven machine learning model, ATOMIC, is accelerating clinical trials, bringing medicines to patients more quickly.
Additional references: Developing Digital Clinical Trials.

How to use it

- Use for enrollment, study design and protocol development.
- Use AI powered chatbots to streamline workflows and create efficiencies throughout the clinical trial process.

Examples

Chatbots can perform time-consuming tasks, virtually and online, including schedule visits, report adverse events, and monitor health status.

Reference: How Chatbots Can be Employed in Clinical Trials?
Additional Reference: Takeda Using Chatbot To Improve Patient-Centricity And Trial Designs.

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

How to use it

- Use for participant recruitment and enrollment.
- 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 Electronic Health Records (EHRs), medical devices, and wearables, and recommend these matches to doctors and potential participants.
- Identify communities in which to engage, learn about different communities and utilize this information to better serve those populations.
- Know where data limitations exists and identify methods to minimize bias.

Examples

AI identified those who received Electrocardiogram (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. 121 primary care teams from 45 clinics or hospitals were identified for participation.

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; Artificial intelligence can improve patients' experience in decentralized clinical trials; Realizing The Potential Of AI And Machine Learning In Clinical Research.

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

How to use it

- Use for study design and protocol development
- Use to design retention strategies- AI technology can pick up specific patient behavioral patterns (Ecological momentary assessment), that may indicate if a patient is likely to dropout; clinical teams can then make adjustments or customize a plan specific to the patient to facilitate retention.
- Enhance patient selection and matching with reducing population heterogeneity by prognostic and predictive enrichment.

Examples

AI and ML used to predict risk behaviors that may indicate the patient may dropout or is experiencing issues with study adherence. AI was used to harmonize Electronic Medical Record (EMR) data and identify patients with a higher probability of specific measurable clinical endpoints.

Reference: Artificial Intelligence for Clinical Trial Design.
Additional References: Artificial intelligence in managing clinical trial design and conduct: Man and machine still on the learning curve?

How to use it

- Use for study design and protocol development.
- Use ML to analyze Real-World Data (RWD) collected from a variety of sources including EHR, claims data, and patient-generated data to develop Real-World Evidence (RWE) to design synthetic control arms.

Examples

Roche used a synthetic control arm of 67 patients to provide the necessary evidence for approval in 20 European countries.

Reference: Comparative effectiveness from a single-arm trial and real-world data: alectinib versus ceritinib.
Additional References: Synthetic and External Controls in Clinical Trials – A Primer for Researchers.

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

How to use it

- Use for study design and protocol development.
- Analyze data in real time to obtain more information on patient preferences and behaviors that may impact retention.
- Track the participant's compliance with the clinical trial's adherence criteria and take predictive and preventive measures as opposed to reactive management to retention risks.

Examples

AI can be used to identify when and which notifications to send to which patients, based on their device use, location and response.

Reference: Artificial intelligence can improve patients' experience in decentralized clinical trials.

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.
- 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.

Tool: Digital Clinical Measures

How to use it

- Use for participant enrollment and recruitment and study design and protocol development.
- Look at previously collected clinical measures for clinical care to design the study and determine populations that should be included.

Examples

Clinical measures range from objectively assessing performance to recording simple vital signs, all of which can be used to optimize clinical studies.

Reference: The role of digital clinical measures in improving cancer care and research.

Additional References: Digital Medicine: A Primer on Measurement; The Playbook Digital Clinical Measures.

How to use it

- Use for participant recruitment and enrollment and study design and protocol development.
- Collect additional participant information, reduce the need for on-site visits, lower costs and participant burdens.

Examples

Remote patient monitoring allows for the collection of medical and other health data from individuals in one location and electronically transmit that information securely to health care providers.

Reference: Advances In mHealth: Remote Monitoring In Clinical Trials.

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 +

- Meet participants where they are.
- Empower and educate participants on research opportunities.
- Increase participants' access to trials.
- Increase trial sponsors and sites' access to participants.
- Expand sources to identify and engage more participants.
- Avoid delays from participants limited experience and knowledge of clinical research opportunities.
- Build a community for participants and begin to build trust.
- Reduce burdens on participants and clinical site.
- Collect additional data relevant participants lifestyle and environment.

Tool: Digital Companion App

How to use it

- Use for participant recruitment and enrollment.
- Use a digital companion app to inform patients of different clinical trials.
- Utilize a digital companion app to give feedback and continuously engage patients, to improve retention rates.

Examples

The University of Kansas Cancer Center has developed a mobile app for iOS and Android that patients can use to identify potential clinical trials.

Reference: Clinical Trial Finder app launched by KU Cancer Center.
Additional References: Medidata reveals patient app to support decentralized trials; Google's new research app shows participants how their data is driving health insights.

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 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.

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: Digital Companion App

How to use it

- Use for study design and protocol development.
- Provide continual engagement in the form of regular study updates, gamification or sharing other information that will allow participants to feel engaged.
- Provide direct-to-patient information and collect patient-generated health data.

Examples

The Brisa app will collect data, analyze it and suggest areas for improvement and tips to help patients better manage their condition.

Reference: Roche partners with Temedica to launch 'digital companion' app for multiple sclerosis.

How to use it

- Use for study design and protocol development.
- Personalize apps based on participant culture, demographics, or clinical trial therapy area.
- Provides a suite of customized and culturally appropriate study materials.

Examples

The NOWINCLUDED app allows patients to learn about trials, receive helpful information about various health topics, and participate in supportive, disease specific communities.

Reference: Nowincluded

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 patients who require advanced therapies.
- Reduce likelihood of trial disruption (e.g., prevent withdrawal, non-adherence, inconclusive study).

How to use it

- Use for participant recruitment and enrollment, and study design and protocol development.
- Track participant engagement behaviors.
- Use to track adherence in real-time to help determine which patients are at risk to drop out or be lost to follow up.

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: 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 as participant engagement, data collection, and administrative management.

Opportunities +

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

How to use it

- Use for participant recruitment and enrollment.
- Use to reach more and diverse participants, without geographic limitations.
- Use for participant outreach, engagement, education, and empowering for health care.

Examples

Through partnerships with digital solutions companies, Janssen is able to design patient-centric trials and foster stronger partnerships with communities.

Reference: How Janssen is Leveraging Thoughtful Technology to Drive Diversity, Equity, and Inclusion.
Additional Reference: Our Health Community; 6 Best Digital Solutions to Accelerate Patient Recruitment.

Tool: Digital Platforms/Solutions for Efficiencies

How to use it

- Use for participant recruitment and enrollment and study design and protocol development.
- Blockchain is a secure and distributed datastore or ledger of ordered records of transactions, with incorruptibility of the data as a core feature. It is a good candidate to provide proof of trust. Such an approach could help improve the transparency and trustworthiness of clinical trials and benefit the whole clinical research ecosystem.

Examples

Blockchain can optimize all steps of the clinical trial process.

Reference: Blockchain enables machine learning and AI to drive a hyper-efficient trial.
Additional References: Applying Blockchain Technology to Enhance Clinical Trial Recruitment.

How to use it

- Use for study design and protocol development.
- Use to automate processes to increase clinical trial efficiencies.
- Use to develop study documents, including Institutional Review Board applications.

Examples

Digital solutions can provide deeper insights which can be used to optimize operational processes and clinical decision making in healthcare.

Reference: Digital platforms for clinical trials: The Eureka experience.
Additional References: Roche adds Navify digital solutions to its digital health portfolio at HLTH 2022; Digital health platforms: Considerations for study design and the IRB.

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.
- Improve engagement for increased retention.
- Streamline workflows and reduce likelihood of trial disruption.
- Improve participant experience, build trust, and demonstrate respect of participant culture and preferences.
- Increase access to diverse participants, for sites and sponsors.
- Increase site and sponsor knowledge of diverse participants.
- Collect additional information for deeper knowledge on participant lived experiences.

Tool: eConsent

How to use it

- Use for participant recruitment and enrollment.
- Allow patients to enroll at a convenient time and place.
- Use to increase rates of enrollment, by reaching additional participants.
- Use to reach participants at different literacy and cognitive levels.
- Customize for specific populations including diverse languages.

Examples

With eConsent the *All of Us* Research Program recruited over 481,000; more than 50% identify as racial and ethnic minorities; more than 80% are from populations considered "underrepresented in biomedical research."

Reference: eConsent Done Right: A Powerful Tool to Build Trust and Diversity in Research.
Additional Reference: E-Consent—a guide to maintain recruitment in clinical trials during the COVID-19 pandemic; Tips for tailoring eConsent for Optimal Patient Centricity.

How to use it

- Use for site selection and site initiation.
- Open the trial to multiples sites and expand the reach of your clinical trial.
- Remove the need for on-site screening visits, save time (and cost) for sites and sponsors; reducing burdens for site workflows and data management.

Examples

The *All of Us* Research Program recruited 481,000 participants nationwide between May 2017 and August 2021. eConsent is effective for reaching diverse populations and being inclusive but specific steps should be taken to do it right.

Reference: eConsent Done Right: A Powerful Tool to Build Trust and Diversity in Research.

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 with providing support to participants.

Tool: On-demand Videos

How to use it

- Use for participant recruitment and enrollment, to recruit sites to participate in the study, for study initiation, 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: 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 on 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.
- 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.
- Streamline workflows for participant engagement, recruitment, and retention.

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

How to use it

- Use for study design and protocol development.
- Use RWD/RWE to design synthetic control arms.
- Use RWD to shorten the time to market and decrease site burdens.
- Optimize study design by matching patients to RWD/RWE from various data sources, including labs, imaging, genetic tests, and physician notes.

Examples

RWD/RWE was used to compare survival outcomes for advanced cancer patients who received complex genomic profiling through a synthetic control arm.

Reference: Comparing Survival Outcomes for Advanced Cancer Patients Who Received Complex Genomic Profiling Using a Synthetic Control Arm.
Additional Reference: Synthetic and External Controls in Clinical Trials – A Primer for Researchers.

How to use it

- Use for participant recruitment and enrollment.
- Use RWD, including electronic health records (EHRs), administrative claims databases, and clinical registries to identify participants suitable for the clinical trial.
- Match patients to protocols, build complex patient cohorts using real world EHR data from various data sources.

Examples

Over 134,000 patients were identified from EHR and study invitations were emailed to existing patients using the clinic patient app.

Reference: Prospective evaluation of smartwatch-enabled detection of left ventricular dysfunction.
Additional reference: Sermonix to Present Updated Data from ELAINE-2 Clinical Trial of Lasofoxifene in Combination with Abemaciclib in Women with Locally Advanced or Metastatic ER+/HER2– Breast Cancer and an ESR1 Mutation after Progression on Prior Therapies at the 2022 ASCO Annual Meeting.

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 meet participants where they are.
- Empower and educate participants on research opportunities.
- Expand opportunities to identify and engage more participants.
- 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.

Tool: Social Media/Digital Marketing

How to use it

- Use for participant recruitment and enrollment, to recruit sites to participate in the study, for study initiation, and throughout study design and protocol development.
- Identify which social media platforms are frequented by your target participant.
- Customize engagement materials and create a guided participant journey.
- 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 who do not have access.

Examples

Social media can increase clinical trial participation 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: 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.
- Increase convenience for participants and site staff, avoid delays with reducing burdens.
- 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.

How to use it

- Use for participant recruitment and enrollment and study design and protocol development.
- Make your trial more accessible and convenient for participants.
- Use for additional data collection.
- Use to increase efficiency and decrease costs for clinical sites.

Examples

Telehealth provides opportunities for brining trials to more participants; thereby demonstrating the power of using this tool in decentralized clinical trials.

Reference: The Role of Telehealth in Decentralized Clinical Trials.

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:

- Artificial Intelligence/Machine Learning (AI/ML)
- Digital Clinical Measures
- Digital Companion App
- Digital Non-Clinical Measures
- Digital Platforms/Solutions for Efficiencies
- eConsent
- On-Demand Videos
- Real World Data/Real World Evidence (RWD/RWE)
- Virtual Visits (Telehealth)

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 +

- More options for identifying drug targets.
- More access to diverse populations.
- More data points.
- 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.
- Learn more about participants lived experiences, begin to build trust.

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

How to use it

- Use for clinical data management and trial monitoring.
- Determine protocol adherence in real time.
- Identify specific patient behavioral patterns, such medication adherence, and predict possible non-compliance during a trial.
- Streamline operational processes by tracking participant health remotely and monitor responses to treatment.
- Use to predict which patients will benefit from the treatment.
- Use to track adverse events.

Examples

ML can be used to analyze data in realtime and identify adherence patterns and extract additional information from other databases.

Reference: Artificial Intelligence for Clinical Trial Design.
Additional References: Identification of type 2 diabetes subgroups through topological analysis of patient similarity; Takeda Using Chatbot To Improve Patient-Centricity And Trial Design.

Tool: Digital 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 +

- 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.
- Increase retention.
- Improve participant experience and build trust.
- Inform disease progression by identifying deteriorating patients who require advanced therapies.
- Streamline workflows 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 or identify other measures that may lead to an adverse event.
- Ensure participants have sufficient resources to fully use clinical measure products, including knowledge on how to use Remote Patient Monitoring (RPM) products, access to internet, and continuous support.

Examples

Clinical measures (i.e. such as RPM) allow 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: 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 +

- Meet participants where they are.
- Empower and educate participants on research opportunities.
- Increase participants' access to trials.
- Increase trial sponsors and sites' access to participants.
- Expand sources to identify and engage more participants.
- Avoid delays from participants limited experience and knowledge of clinical research opportunities.
- Build a community for participants and begin to build trust.
- Reduce burdens on participants and clinical site.
- Collect additional data relevant participants lifestyle and environment.

Tool: Digital Companion App

How to use it

- Use for clinical trial monitoring.
- Use to monitor studies and offer continuous engagement with patients while reinforcing behavior for study adherence.
- Track participant engagement to determine which participants are at risk of dropping out/being lost to follow-up.
- Modify workflows to better support participants.

Examples

Patients utilizing the digital companion app showed a 7% increased adherence compared to those who did not use the app.

Reference: Komodo Health Study: Medisafe Digital Companion Increases Adherence and Persistence.

How to use it

- Use for clinical data management.
- Use for real-time, passive data collection (patient generated health data).

Examples

The Brisa app collects daily health data, including sleep, activity and dietary habits, and allow patients to track symptoms associated with their condition.

Reference: Roche partners with Temedica to launch 'digital companion' app for multiple sclerosis.

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 or identify additional factors that may lead to adverse events.
- 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: 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.
- More access to diverse populations.
- Reach participants at multiple sites concurrently
- Increase participants' access to trials.
- Increase trial sponsors and sites' access to participants.

Tool: Digital Platforms/Solutions for Efficiencies

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.

How to use it

- Use for clinical data management and trial monitoring.
- Use to increase efficiencies by allowing for automation and the collection of more data without the need for participant or clinical team intervention.

Examples

The clinical data platform allows for seamless data collections which can then be used to design randomized clinical trials.

Reference: Verily, Stanford and Duke kick off Project Baseline study to develop broad reference of human health;
Additional Reference: Scripps Research Digital Trials Center “Wrapped”: A year in review across our research platforms

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.

Tool: eConsent

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: 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 with providing support to participants.

How to use it

- Use for clinical data management and trial monitoring.
- Use videos to interact with participants and learn about their environment and lifestyle, which can impact participation and trial outcomes.
- Use to collect qualitative data to support the quantitative data.
- Use to create patient-centric efficiencies for trial management, including providing continuous education and updates, which can lead to retention and complete data collection.

Examples

Videos can capture patient activities and provide meaningful insights to accompany and enhance endpoints and reduce burdens including traveling to clinical sites.

Reference: Time to See the Difference: Video Capture for Patient-Centered Clinical Trials.

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 +

- 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 engagement for increased retention.
- Improve participant experience and build trust.
- Streamline workflows and reduce likelihood of trial disruption (e.g., prevent withdrawal, non-adherence, inconclusive study).
- Reduce sample sizes, increase study power, and reduce costs with richer data for each participant.

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

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: 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.
- Increase convenience for participants and site staff, avoid delays with reducing burdens.
- 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.

How to use it

- Use for clinical data management and trial monitoring.
- Use for more frequent check ins and additional support for participants while reducing burdens on clinical staff and participants.

Examples

Patients assisted via virtual visits showed significant improvements with diabetes self management.

Reference: Telemedicine-Assisted Self-Management Program for Type 2 Diabetes Patients.

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.

Digital Tools:

- Artificial Intelligence/Machine Learning (AI/ML)
- Digital Clinical Measures
- Digital Companion App
- Digital Non-Clinical Measures
- Digital Platforms/Solutions for Efficiencies
- eConsent
- On-Demand Videos
- Real World Data/Real World Evidence (RWD/RWE)

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.

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

How to use it

- Use for statistical analysis and final reporting.
- Use to format data and highlight key findings for final write up and regulatory filings.

Examples

Machine-learning analysis may also be able to improve the quality of regulatory submissions by identifying the most likely requests for information that government regulators may have and incorporating the answers from the get-go.

Reference: Artificial Intelligence: On a mission to Make Clinical Drug Development Faster and Smarter.

How to use it

- Use for clinical data management and trial monitoring.
- Use for more frequent check-ins and additional support for participants while reducing burdens on clinical staff and participants.

Examples

Patients assisted via virtual visits showed significant improvements with diabetes self management.

Reference: Telemedicine-Assisted Self-Management Program for Type 2 Diabetes Patients.

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.
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Tool: Digital Clinical Measures

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.

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

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 for future studies.

Examples

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

Reference: What The Fitbit Is Helping Pharma Learn About Patients.

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 research studies.

Opportunities +

- Meet participants where they are.
- Empower and educate participants on research opportunities.
- Increase participants' access to trials.
- Increase trial sponsors and sites' access to participants.
- Expand sources to identify and engage more participants.
- Avoid delays from participants limited experience and knowledge of clinical research opportunities.
- Build a community for participants and begin to build trust.
- Reduce burdens on participants and clinical site.
- Collect additional data relevant to participants lifestyle and environment.

How to use it

- Use for statistical analysis and final reporting.
- Use additional information collected by the app to provide context to the quantitative metrics and enrich the data collected for the trial.

Examples

Participant reported outcomes were analyzed along with sensor metrics to gain deeper information on variability by patient and specific symptoms.

Reference: Wearable sensor data and self-reported symptoms for COVID-19 detection.

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 +

- Identify innovative therapies to advance health equities.
- Increase opportunities to collect additional and more relevant measures.
- Improve outcomes and increase likelihood of technical success.
- 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.
- Use additional information on participant environment and lifestyle to more comprehensively analyze treatment effectiveness and adherence.
- Add depth to trial specific data with more rigorous and informed analysis.

Examples

Utilizing a carbon monoxide meter with the app allowed patients to measure how much harmful CO is accumulated in their body, and influenced their cessation behaviors.

Reference: A Novel Smoking Cessation Smartphone App Integrated With a Mobile Carbon Monoxide Checker for Smoking Cessation Treatment: Protocol for a Randomized Controlled Trial.

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 as 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.

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- Increase access to diverse participants, for sites and sponsors.
- Increase site and sponsor knowledge of diverse participants.

Tool: eConsent

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. if there are additional items for patients to opt in and out of, behavioral details- time to complete, click through rate, cultural elements - 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. For example, if the eConsent took a significantly longer time to complete for older adults, perhaps this is an opportunity to optimize the content to increase enrollment rates.

Examples

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- 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 with providing support to participants.

How to use it

- Use for statistical analysis and final reporting.
- Use to obtain more data points and qualitative information to better assess trial outcomes.

Examples

Video can capture patient activities and provide meaningful insights to accompany and enhance endpoints and reduces burdens including traveling to clinical sites.

Reference: Time to See the Difference: Video Capture for Patient-Centered Clinical Trials

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

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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.