DIVERSITY, EQUITY, & INCLUSION
in Digitized Clinical Trials

DiME
DIGITAL MEDICINE SOCIETY

Specific Actions to Enroll & Retain Diverse Participants

A Digital Tools Workbook

Design a person-centered strategy with digital tools to increase diversity, equity, and inclusion in clinical trials

Digital tools are providing new opportunities and innovations to tackle some of the biggest hurdles facing the clinical trials ecosystem. When integrated with a person-centered strategy, digital tools can facilitate improvements with diversity, equity, and inclusion.

1 Assess

Assess opportunities for utilizing digital tools to be more diverse, equitable, and inclusive with your clinical trial design

2 Identify

Identify which digital tools are best suited to each step of your design process

3 Implement

Implement the person-centered principles

- **Diversity** is critically needed, due to decades-long lack of equity
- **Inclusivity** must be central to each step in the clinical trial lifecycle
- **Accountability** is a requirement for success

According to the WHO, **person centered** is focused on and organized around the person's needs, values, preferences, and expertise based on their personal experiences. A person-centered strategy will acknowledge and address the person who is living with a condition, in the context of their lives, families, and communities.

Assess opportunities for utilizing digital tools to be more diverse, equitable, and inclusive with your clinical trial design

Specific Action

Start with **a comprehensive definition of diversity, equity, and inclusion**. Each term carries specific meaning and impact for clinical trials. Follow the **steps of digitized clinical trials** to learn how to implement different digital tools to best support your clinical trial process.

Opportunities for Diversity, Equity, & Inclusion +

- Increase efficiencies for participant engagement, enrollment, and retention
- Accelerate timelines and improve workflow efficiencies
- Increase applicability of results to broader populations
- Build trust and increase credibility among participants
- Improve reputation of clinical trials industry

Target Users 👥

Biopharma and medical device companies, Clinical research organizations, Decentralized clinical trial organizations, Healthcare researchers, Regulators, Data scientists/managers, Ethicists, Clinician scientists, Patient advocates, and Patient engagement professionals, Clinical trial sponsors, Clinical trial sites

Access Resources 📥

Define Diversity, Equity, and Inclusion in Clinical Trials

Implement a Digitized Clinical Trial Process

Assess opportunities for utilizing digital tools to be more diverse, equitable, and inclusive with your clinical trial design

Specific Action

To optimize digital tools with improving your clinical trial outcomes, you first need to identify where to focus your efforts. Learn the **benefits of applying digital tools** to address challenges at each step of the clinical trials life cycle and the opportunities to focus on **specific needs for increased diversity, equity, and inclusion**. Consult **evidence-based resources** and references for guidance.

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Digital Tools 🛠

1. Digital Solutions
2. Digital Platforms

Access Resources 📥

Address Clinical Trial Challenges

Recognize the Need for Diversity

Evidence-Based References and Resources Supporting Diversity, Equity, and Inclusion

Identify which digital tools are best suited to each step of your design process

Specific Action

Digital tools have great potential for transforming the clinical trials industry with streamlining workflows, increasing and improving data collections, and decreasing costs. Each element of a **digitized clinical trial can be supported by multiple digital tools**.

Opportunities for Diversity, Equity, & Inclusion +

- Accelerate timelines and improve workflow efficiencies

- Increase efficiencies for participant engagement, enrollment and retention

- Increase applicability of results to broader populations

- Improve outcomes and increased likelihood of technical success

- Identify and develop innovative therapies to advance health equity

Target Users 👥

Clinical operations, Decentralized clinical trial and Clinical research organizations, Clinical trial sites

Digital Tools 🛠️

1. AI/ML   2. RWD/RWE

3. eConsent   4. Digital clinical measures

5. Non-clinical measures

6. Virtual visits7. On-demand videos

8. Digital companion app

9. Digital campaign/social media

10. Digital platforms/solutions

Access Resources 📥

Elements of a Digitized Clinical Trial

Applications of Digital Tools - Expanded

Implement the person-centered principles:
Diversity for equity: Diversity will mitigate gaps caused by inequities

Specific Action

Identify populations on the community and individual levels **that will benefit the most** from your therapeutic area or clinical trial. Analyze RWD/RWE to identify those participants who match inclusion and exclusion criteria.

Opportunities for Diversity, Equity, & Inclusion **+**

- Increase access and awareness for participants to clinical trial participation

- Increase clinical trial designers and implementers access of and knowledge to diverse populations

- Increase and improve patient engagement and retention

- Reduce burdens for participants and clinical trial teams by streamlining and creating efficiencies with awareness and outreach

- Build trust by working directly with diverse communities

- Accelerate recruitment timelines with fewer participants needed for analysis, decreased time lost to participant screening, and overall streamline recruitment processes for participants and clinical teams

- Collect more relevant measures and non-clinical measures which can lead to improved outcomes and more robust data

Target Users 👥

Clinical operations, Decentralized clinical trial and Clinical research organizations, Clinical trial sites

Digital Tools 🛠

1. RWD/RWE
2. AI/ML

Access Resources 📥

Use Real-World Data and Real-World Evidence

Use the Market Opportunity Calculator

Implement the person-centered principles:
Inclusivity: Inclusion is a foundation for each step in the trial lifecycle

Specific Action

Design and **implement intentional strategies** to engage diverse populations coupled with actions to ensure all participants feel included. Develop a **inclusive outreach and engagement** plan with a process for continuous engagement to encourage, support, and meet all participants where they are and with what they need to participate fully.

Opportunities for Diversity, Equity, & Inclusion +

- Increase access and awareness for participants to clinical trial participation
- Increase and improve patient engagement, enrollment, and retention
- Reduce burdens for participants and clinical trial teams by streamlining and creating efficiencies with awareness and outreach
- Increase access of and knowledge for clinical trial designers and implementers to diverse populations
- Build trust by demonstrating interest in working directly with diverse communities
- Accelerate recruitment timelines

Target Users 👥

Clinical operations, Decentralized clinical trial and Clinical research organizations, Clinical trial sites, Marketing and communications professionals, Patient advocacy and engagement professionals

Digital Tools 🛠

1. Digital campaign
2. Digital companion app
3. Digital solutions
4. On-demand videos
5. Virtual visits

Access Resources 📥

Plan for Diverse, Equitable, and Inclusive Engagement

Design an Inclusive Engagement Plan

Implement the person-centered principles:
Inclusivity: Inclusion is a foundation for each step in the trial lifecycle

Specific Action

Create an **empowering experience for participants**. Ensure that participants have all the resources and tools they need to fully participate, before implementing clinical trial processes. This includes tools for inclusive participation and participant education.

Opportunities for Diversity, Equity, & Inclusion **+**

- Reduce burdens for participants and clinical trial teams by streamlining processes and including participants as partners

- Increase compliance and participant adherence

- Improve outcomes with more robust data collection

- Increase and improve patient engagement and retention

- Build trust and transparency between participants, Sponsors, and clinical trial teams for long-term engagement with clinical trials and research

- Increase access and awareness for participants to clinical trial participation

- Increase awareness for participants on clinical trial participation value and process

Target Users 👥

Clinical operations, Decentralized clinical trial and Clinical research organizations, Clinical trial sites, Marketing and communications professionals, Patient advocacy and engagement professionals

Digital Tools 🛠️

1. eConsent
2. On-demand videos
3. Digital companion app
4. Digital solutions, virtual visits
5. Clinical and non-clinical digital measures

Access Resources 📥

Empower Through eConsent

Empower With Information and Education

Implement the person-centered principles:
Inclusivity: Inclusion is a foundation for each step in the trial lifecycle

Specific Action

Demonstrate a **commitment to building trust and credibility**. Sustained efforts to increase diversity and improve equity and inclusivity in clinical trials starts with building trust. Implement a three pronged approach: community partnerships, representative clinical teams, and clinical trial participant support network.

Opportunities for Diversity, Equity, & Inclusion +

- Build trust and transparency between participants and sponsors and clinical trial teams for long-term engagement with clinical trials and research
- Increase and improve patient engagement and retention
- Reduce burdens for participants and clinical trial teams by streamlining processes and including participants as partners
- Improve outcomes with more robust data collection
- Increase access and awareness for participants to clinical trial participation
- Increase awareness for participants on clinical trial participation value and process

Target Users 👥

Clinical operations, Decentralized clinical trial and Clinical research organizations, Clinical trial sites, Marketing and communications professionals

Digital Tools 🛠

1. RWD/RWE, AI/ML   2. Digital campaign   3. Digital companion app   4. Digital solutions   5. On-demand videos 6. Virtual visits

Access Resources ⬇

Develop Community Partnerships to Build Trust

Diversify Clinical Teams to Build Trust

Develop a Virtual Participant Support Network to Build Trust

Implement the person-centered principles:
Inclusivity: Inclusion is a foundation for each step in the trial lifecycle

Specific Action

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.

Opportunities for Diversity, Equity, & Inclusion +

- Build trust and transparency, and strengthen relationships between Sponsors and clinical trial teams
- Reduce burdens for clinical trial teams and participants by streamlining processes and including participants as partners
- Increase compliance and participant adherence
- Improve outcomes with more robust data collection
- Increase and improved patient engagement and retention
- Increase access and awareness for participants to clinical trial participation
- Increase awareness for participants on clinical trial participation value and process

Target Users 👥

Clinical operations, Decentralized clinical trial and Clinical research organizations, Clinical trial sites

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Access Resources 📥

Support and Train Clinical Trial Site Staff

Hire a Digital Clinical Trials Navigator

Implement the person-centered principles:
Accountability: Demonstrate commitment for sustainable progress

Specific Action

Demonstrate your commitment to diversifying clinical trials by tracking your efforts to increase diversity, equity, and inclusion. Develop a system with metrics to ensure that diverse participant enrollment goals are met, per the FDA Diversity Plan requirement.

Opportunities for Diversity, Equity, & Inclusion **+**

- Demonstrate commitment to eradicating health disparities and advancing health equity

- Build trust and transparency across the clinical trials ecosystem for improved processes and long-term engagement and commitment to clinical research

- Improve credibility as a leader in the clinical trials ecosystem

- Improve participation and reputation of clinical trials industry

- Create more efficient post-market surveillance and inform future studies

Target Users 👥

Biopharma and medical device companies, Clinical research organizations, Decentralized clinical trial organizations, Healthcare researchers, Regulators, Data scientists/managers, Ethicists, Clinician scientists, Patient advocates, and Patient engagement professionals, Clinical trial sponsors, Clinical trial sites

Digital Tools 🛠

1. AI/ML

2. RWD/RWE

3. Digital platforms/solutions

Access Resources 📥

Design a Diversity Dashboard

Implement the person-centered principles:
Accountability: Demonstrate commitment for sustainable progress

Specific Action

Take action now and start to include digital tools to diversify clinical trials by using the resources created by the Diversity, Equity, and Inclusion in Digitized Clinical Trials multi-stakeholder project team. The project team exemplifies the value of partnership and collaboration from across the clinical trials ecosystem.

Opportunities for Diversity, Equity, & Inclusion +

- Build trust and transparency across the clinical trials ecosystem by committing to improving processes and long-term engagement and commitment to clinical research

- Demonstrate commitment to eradicating health disparities and advancing health equity

- Improve credibility as a leader in the clinical trials ecosystem

- Improve participation and reputation of clinical trials industry

Target Users 👥

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Digital Tools 🛠️

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9. Digital campaign/social media
10. Digital platforms/solutions
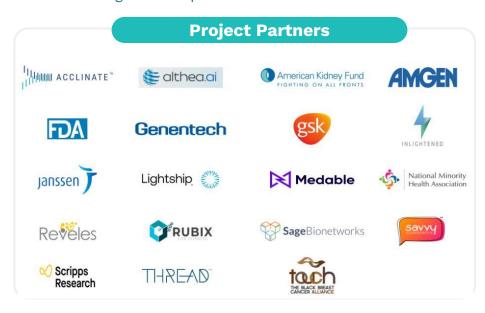
Access Resources 📥

Resources in Action

Acknowledgments

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Diversity is receiving an invitation to a party. **Equity** is possessing the resources to attend. **Inclusion** is being asked to dance. – Author Unknown