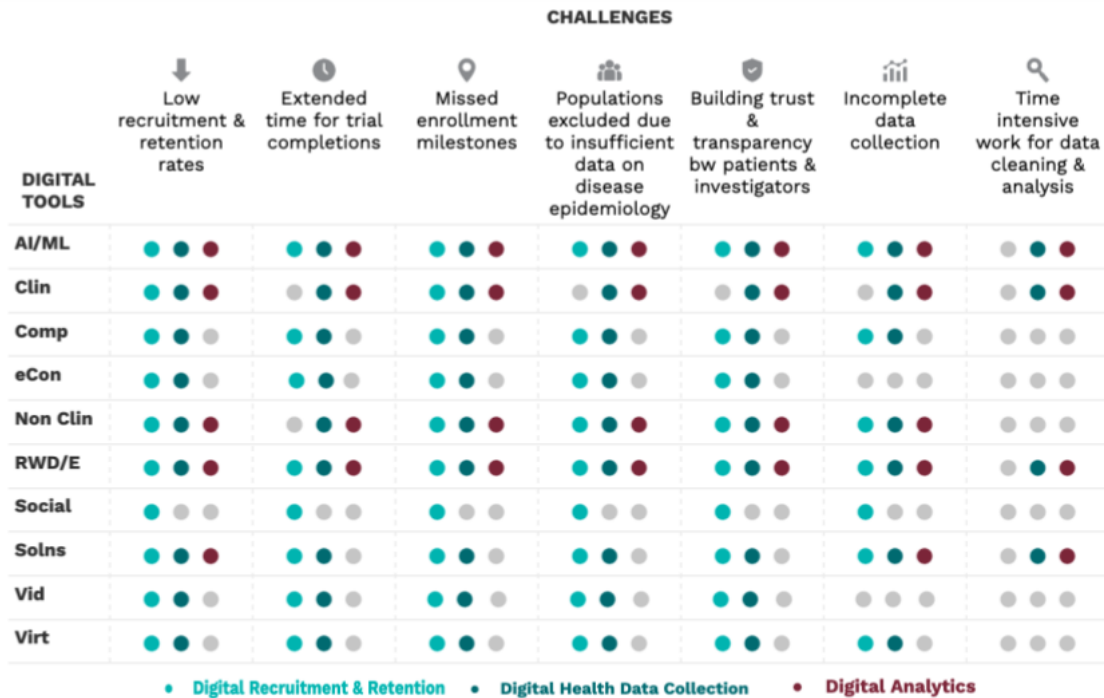


# Address Clinical Trial Challenges



## What should I do?

Identify which digital tools are best suited for addressing specific challenges at each step of the clinical trials process. Learn the benefits of applying digital tools to address specific challenges and the opportunities to focus on specific needs for increased diversity, equity, and inclusion. Consult [evidence based references and resources](#) for guidance.

## Why should I do it?

- Improve and increase engagement, enrollment and retention.
- Accelerate timelines and improve workflow efficiencies.
- Increase applicability of results to broader populations.

### Ethical Considerations

While there is growing evidence that digital tools can improve the clinical trial industry and increase representation, we need to be cognizant of the inequities of the digital divide. With using these digital tools, we are also responsible for ensuring that all potential participants have equitable access, knowledge, and the confidence required to use these digital technologies fully.

**Digital tools** have potential for transforming the clinical trials industry, with **streamlining workflows, increasing and improving data collections, and decreasing costs**. With these tools, clinical trials can evolve into a network of stakeholders working together to improve study efficiencies and quality and to accelerate the development of new therapies. Clinical trial participants will be at the center of this transformation, as digital tools will also provide opportunities to increase diversity and inclusion, and ultimately advance health equity.

A person-centered approach for clinical trials will mean better participant engagement, greater access, more efficient processes, and more robust data to inform health outcomes.

Several digital tools are leading this transformation: Artificial Intelligence/Machine Learning methodologies (AI/ML), digital companion app, digital clinical measures, digital non-clinical measures, eConsent, on demand videos, Real World Data/Evidence (RWD/RWE), social media/digital marketing, virtual visits, and digital platforms for efficiencies/digital solutions. See the “[Elements of a Diverse, Equitable, and Inclusive Digital Clinical Trial](#)” for details on using each of these tools.

Jump to

- [Digital Tools Opportunity Matrix](#)
- [Specific Opportunities To Accelerate, Diversify, Personalize, And Lead Cost-Effective Clinical Research](#)



## Digital Tools Opportunity Matrix

The **Opportunity Matrix** aligns challenges facing clinical trials with specific digital tools and opportunities for each step of the digitized clinical trial process.

DIGITAL TOOLS	CHALLENGES						
	Low recruitment & retention rates	Extended time for trial completions	Missed enrollment milestones	Populations excluded due to insufficient data on disease epidemiology	Building trust & transparency bw patients & investigators	Incomplete data collection	Time intensive work for data cleaning & analysis
AI/ML	●●●	●●●	●●●	●●●	●●●	●●●	●●●
Clin	●●●	●●●	●●●	●●●	●●●	●●●	●●●
Comp	●●●	●●●	●●●	●●●	●●●	●●●	●●●
eCon	●●●	●●●	●●●	●●●	●●●	●●●	●●●
Non Clin	●●●	●●●	●●●	●●●	●●●	●●●	●●●
RWD/E	●●●	●●●	●●●	●●●	●●●	●●●	●●●
Social	●●●	●●●	●●●	●●●	●●●	●●●	●●●
Solns	●●●	●●●	●●●	●●●	●●●	●●●	●●●
Vid	●●●	●●●	●●●	●●●	●●●	●●●	●●●
Virt	●●●	●●●	●●●	●●●	●●●	●●●	●●●

### DIGITAL TOOLS

- AI/ML** Artificial Intelligence/Machine Learning
- Clin** Digital Clinical Measures
- Comp** Digital Companion App
- eCon** eConsent
- Non Clin** Digital Non Clinical Measures
- RWD/E** Real World Data/Evidence
- Social** Social Media/Digital Marketing
- Solns** Digital Platforms/Solutions for Efficiencies
- Vid** On Demand Videos
- Virt** Virtual Visits (Telehealth)

### OPPORTUNITY KEY

- **Digital Recruitment & Retention**  
Improve & increase engagement, enrollment & retention
- **Digital Health Data Collection**  
Accelerate timelines & improve workflows
- **Digital Analytics**  
Increase applicability of results to broader populations



## Specific Opportunities To Accelerate, Diversify, Personalize, And Lead Cost-Effective Clinical Research

1. **Digital recruitment and retention** - opportunities for **increasing efficiencies for engagement, enrollment and retention**:
  - a. Increase access to clinical trials for participants,
  - b. Increase access to diverse participants, for sites and sponsors,
  - c. Increase site and sponsor knowledge of diverse participants,
  - d. Increase and improved engagement for enrollment,
  - e. Increase opportunities to build trust and improve participant experience,
  - f. Decrease time needed for participant outreach, engagement and enrollment,
  - g. Improve participation and reputation of the clinical trials industry.
2. **Digital health data collection** - opportunities for **accelerating timelines and improving workflow efficiencies**:
  - a. Increase access to diverse participants, for sites and sponsors,
  - b. Increase site and sponsor knowledge of diverse participants,
  - c. Increase and improved engagement for retention,
  - d. Reduce sample sizes,
  - e. Increase study power,
  - f. Reduce cost,
  - g. Increase opportunities to collect additional and more relevant measures,
  - h. Decrease trial drop-out and non-compliance (study adherence),
  - i. Decrease time to determine intervention effects,
  - j. Increase opportunities to build trust and improve participant experience,
  - k. Streamline enrollment and retention process for site staff,
  - l. Streamline workflows with data collection, documentation and tracking,
  - m. Create more accessible, affordable, timely, and scalable participant-centric research,
  - n. Inform disease progression by identifying deteriorating patients who require advanced therapies,
  - o. Reduce likelihood of trial disruption (e.g., prevent trial drop out, non-adherence, inconclusive study),
  - p. Improve collaborations across the clinical trial ecosystem.



3. **Digital analytics** - opportunities for **increasing applicability of results to broader populations:**
  - a. Better inform go/no-go regulatory, and reimbursement strategy and decisions,
  - b. Improve outcomes and increased likelihood of technical success,
  - c. Identify and develop innovative therapies to advance health equities,
  - d. Create more efficient post-market surveillance and inform future studies.





## References & Resources

1. [A Digital Redesign for Clinical Trials](#). With the explosion of EHRs and the penetration of both mobile technology and the Internet of Things, the right conditions are in place for digital innovation in clinical trials.
2. [A Winning Strategy Shaping Pharma's Digital Health Transformation](#). Digital health is adding value across all aspects of the drug value chain, including clinical research & drug discovery, lifecycle management, product commercialization, and beyond-the-molecule initiatives.
3. [Accelerating Momentum: Digital innovation in clinical trials](#). Accelerating adoption is a top priority for biopharma organizations, with some key areas seen as driving the most value.
4. [Digitally Enabled, Patient-Centric Clinical Trials: Shifting the Drug Development Paradigm](#). The rapidly advancing field of digital health technologies provides a great opportunity to radically transform the way clinical trials are conducted and to shift the clinical trial paradigm from a site-centric to a patient-centric model.
5. [Digital Health Products Can Reduce Healthcare Disparities — If We Take Action](#). While there is potential for digital health to be the vehicle in which we can move toward a more equitable healthcare system, addressing gaps in care to achieve greater equality will require multifaceted solutions and collaboration to create and implement meaningful and sustainable change.
6. [Digital tools driving innovative clinical trials](#). Digital technologies will revolutionize medicine and have a substantial impact on clinical trials.
7. [How Digital Connections Can Create a Positive Patient Experience in Clinical Trials](#). Digitally-enabled clinical trials can improve the patient experience.
8. [How Technology Is Helping Increase Diversity In Clinical Trials](#). One of the main reasons participation in clinical trials has come such a long way is because of the prevalence of technology to measure and capture health-related data.
9. [Integrating Diversity, Equity, & Inclusion Throughout Clinical Trials](#). While it may appear obvious that the implications of DEI are especially critical within drug development and clinical trials, many organizations have struggled to mobilize their organizations to take tangible steps to reach their related DEI aims.
10. [The Playbook, Digital Clinical Measures](#). The Pharma Exec dossier contains resources to support executive decision makers within pharma to champion the appropriate use of digital clinical measures.
11. [The Promise of Digital Health: Then, Now, and the Future](#). Revolutionary advances in digital health are transforming health, medicine, and biomedical science, and redefining and re-engineering the tools needed to create a healthier future.



12. [Two Straightforward Ways To Improve DE&I In Clinical Trials](#). We have the tools to begin to address the lack of trust and limited data and incorporate them into diversity plans for clinical trials today.
13. [What is patient centricity in clinical trials?](#) From recruitment to randomization, the patient journey is a driving force in all that we do.
14. [WHO global strategy on integrated people-centered health services 2016-2026](#). The World Health Organization (WHO) global strategy on integrated people-centered health services is a call for a fundamental paradigm shift in the way health services are funded, managed and delivered.

