Clinical and Translational Science

PERSPECTIVE OPEN ACCESS

Bridging Implementation Gaps in Digital Health: A Translational Research Imperative for Equitable Healthcare Innovation

Laiba Husain[1] | Katherine Kitchens[1] | Saroop Raja[2] | Madiha Memon[3]

[1]Department of Social and Behavioural Sciences, Peter O'Donnell Jr. School of Public Health, University of Texas Southwestern Medical Center, Dallas, Texas, USA | [2]Birmingham and Solihull Mental Health Foundation Trust, Birmingham, UK | [3]Oxford University Hospital NHS Foundation Trust, Oxford, UK

Correspondence: Laiba Husain (laiba.husain@utsouthwestern.edu)

Received: 29 May 2025 | **Revised:** 16 September 2025 | **Accepted:** 22 September 2025

Funding: The authors received no specific funding for this work.

Keywords: digital health | health equity | implementation science | precision implementation | translational research

ABSTRACT

Digital health technologies' potential to democratize healthcare access appears constrained by implementation challenges that may reproduce existing inequities. This paper examines systemic barriers potentially impeding translation, suggesting prevailing frameworks inadequately address structural determinants. Despite substantial investment, limited FDA approvals for digital-derived endpoints indicate possible regulatory-innovation disjunctures, while constrained funding and incomplete reimbursement structures systematically exclude essential services. We propose a precision implementation framework repositioning implementation science as integral to technological development, potentially challenging linear translational paradigms. This approach emphasizes examining sociotechnical systems, organizational readiness variations, and community-specific contexts. Whether digital health mitigates or exacerbates disparities likely depends on reconceptualizing implementation as socio-organizational transformation requiring regulatory harmonization, sustainable economic models, and equity-centered engagement.

1 | Introduction

Digital health technologies represent a promising frontier in modern medicine, offering unique opportunities to democratize healthcare access and improve outcomes across diverse populations. Despite rapid technological advancement and substantial investment in digital therapeutics, remote monitoring, and artificial intelligence applications, the translation of these innovations into equitable, sustainable healthcare improvements remains incomplete. This translational gap reflects fundamental challenges in how the field approaches the implementation science of digital health innovation.

2 | The Promise and Paradox of Digital Health Translation

The COVID-19 pandemic accelerated certain aspects of digital health adoption, most notably the widespread implementation of telehealth video visits, which increased from less than 1% of healthcare visits pre-pandemic to over 85% during peak pandemic periods in some health systems [1]. Remote patient monitoring for COVID-19 symptoms and pulse oximetry also saw expanded use, and digital contact tracing applications were deployed globally, though with variable success rates [2]. However, this rapid deployment—primarily concentrated in telehealth

Clinical and Translational Science, 2025; 18:e70375
https://doi.org/10.1111/cts.70375

consultations—exposed critical implementation barriers that disproportionately affected vulnerable populations [1], while other digital health technologies such as decentralized clinical trials, continuous physiological monitoring, and AI-driven diagnostics saw limited expansion beyond research settings [3].

The pandemic experience revealed both the potential and limitations of digital health scaling. Rural communities, older adults, and socioeconomically disadvantaged groups experienced significant challenges accessing and effectively utilizing even basic telehealth services [4], raising concerns that these technologies may inadvertently widen existing health disparities rather than narrow them [2].

Traditional approaches to digital health implementation have emphasized device functionality, user interface design, and clinical efficacy in controlled settings [5]. While these elements remain important, they appear insufficient for achieving sustained, equitable implementation across diverse healthcare contexts. A more comprehensive implementation framework that integrates technological innovation with a robust understanding of sociotechnical systems, organizational readiness, and community contexts is necessary.

This perspective suggests fundamental changes in how translational research is conceptualized and conducted. Rather than viewing implementation as a final phase following successful clinical trials, implementation considerations could be embedded throughout the entire translational continuum, from early-stage technology development through post-market surveillance and optimization. Such an approach aligns with the National Center for Advancing Translational Sciences' emphasis on addressing bottlenecks that impede the translation of scientific discoveries into improved health outcomes [2].

3 | Economic and Systemic Barriers: The Hidden Impediments to Digital Health Adoption

Beyond the implementation science considerations traditionally emphasized in translational research, digital health adoption faces fundamental economic and regulatory barriers that may represent more significant obstacles to widespread implementation than previously recognized. These systemic challenges illuminate why some digital health technologies struggle to achieve sustainable adoption in routine healthcare delivery.

The mainstream adoption of digital health technologies has been primarily driven by pharmaceutical industry-sponsored clinical trials and federal grant-based academic research, creating an investment ecosystem that undermines its own sustainability by generating substantial costs without corresponding regulatory approvals or sustainable revenue streams. Despite substantial industry investment in digital health tools for drug development—estimated at over $4.2 billion annually—the lack of regulatory approvals for novel therapeutics where digital technology-derived measures constitute the primary or key secondary efficacy endpoints has created significant industry reluctance to continue adoption [6]. By digital technology-derived measures, we refer to endpoints captured exclusively through digital health technologies such as accelerometer-based activity measures, smartphone-derived gait assessments, or digital cognitive testing platforms, as distinct from digitally enabled traditional biomarkers (e.g., continuous glucose monitors that rely on biochemical reactions but transmit data digitally). This disincentive effect is particularly pronounced given the substantial costs associated with digital health implementation, including technology integration, staff training, and ongoing maintenance requirements that can exceed $500,000 per trial for complex digital endpoint programs [7].

The regulatory approval challenge extends beyond individual trials to systemic issues with validation pathways for digitally derived measures. While there remains ongoing scientific debate regarding the classification of digitally derived measures as either biomarkers or clinical outcome assessments, FDA data indicates that the vast majority of applications for digitally derived measures are classified as clinical outcome assessments rather than biomarkers. Regardless of classification, the fundamental challenge persists: while the FDA has provided guidance on digital health technologies for remote data acquisition, no major therapeutic has received approval based primarily on digital technology-derived primary endpoints, creating a fundamental disconnect between industry investment and regulatory recognition [8]. This regulatory gap perpetuates a cycle where pharmaceutical sponsors invest in digital tools for secondary endpoints or exploratory measures but remain hesitant to stake primary efficacy claims on digital technologies.

Recent biomedical research federal funding constraints in the United States compound these challenges by limiting academic institutions' capacity to conduct the foundational research necessary for digital health validation and optimization. The National Institutes of Health budget has remained relatively flat in inflation-adjusted terms since 2012, while digital health research demands have increased exponentially [5].

The funding constraints disproportionately impact digital health research because these studies often require multidisciplinary expertise spanning engineering, clinical science, and implementation research—collaborations that are difficult to support within traditional NIH funding mechanisms designed for single-discipline investigations [6]. Academic medical centers, already facing financial pressures from decreased clinical revenues and increased operational costs, have limited capacity to internally fund the technological infrastructure and expertise required for advanced digital health research.

Perhaps most critically, the absence of comprehensive reimbursement frameworks represents the fundamental barrier to sustainable digital health adoption in routine clinical practice. While recent policy developments have introduced limited billing codes—such as CMS's 2025 HCPCS codes G0552–G0554 for digital mental health treatment devices—these cover only psychiatric conditions and fail to address the broader ecosystem of support services required for digital health deployment [7].

Healthcare providers consistently identify reimbursement gaps as the primary obstacle to digital health adoption, specifically citing the lack of billing codes for essential support services including patient training and education, IT helpdesk support, troubleshooting, and care coordination activities that digital health tools require [8].

These services, while essential for successful implementation, fall outside traditional fee-for-service models designed for in-person clinical encounters. A typical digital therapeutic implementation requires an average of 2.5 h of initial patient training, 45 min of monthly maintenance support, and 1.2 h of technical troubleshooting per patient per year—none of which are currently reimbursable under standard healthcare payment models [9].

The economic burden extends beyond direct service provision to include infrastructure costs for data management, cybersecurity compliance, and interoperability maintenance that healthcare organizations must absorb without compensation. Small and medium-sized healthcare practices, which represent the majority of primary care delivery in the United States, lack the financial capacity to absorb these unreimbursed costs, creating a fundamental barrier to equitable digital health access [10].

This economic reality indicates that translational research efforts may need to prioritize developing business models and payment mechanisms alongside clinical validation, recognizing that sustainable implementation depends as much on financial viability as on clinical effectiveness. The field may benefit from research focused on value-based payment arrangements, shared savings models, and alternative reimbursement structures that can support the comprehensive care ecosystem that digital health technologies require.

4 | The Implementation Science Framework

Implementation science provides frameworks for understanding and addressing the complex, multilevel factors that influence digital health adoption and sustainability. Constructs such as acceptability, appropriateness, feasibility, and sustainability offer structured approaches to identifying and addressing implementation barriers before they become obstacles to equitable access [2]. Recent advances in digital health evaluation frameworks, particularly the community-developed Digital Medicine Society's V3+ Framework, have extended traditional verification, analytical validation, and clinical validation processes to include usability validation. While this framework is consistent with FDA guidance on digital health technologies for remote data acquisition, it represents an industry-led standardization effort rather than a regulatory requirement, aimed at ensuring digital health technologies meet user needs at scale [6]. This evolution recognizes that technical performance alone is insufficient for successful implementation—technologies must also demonstrate acceptable user experience, workflow integration, and sustained engagement across diverse populations and settings.

As illustrated in Figure 1, the precision implementation approach recognizes that barriers occur at multiple levels and stages of translation. Economic barriers like reimbursement gaps persist across all phases, while technical barriers such as

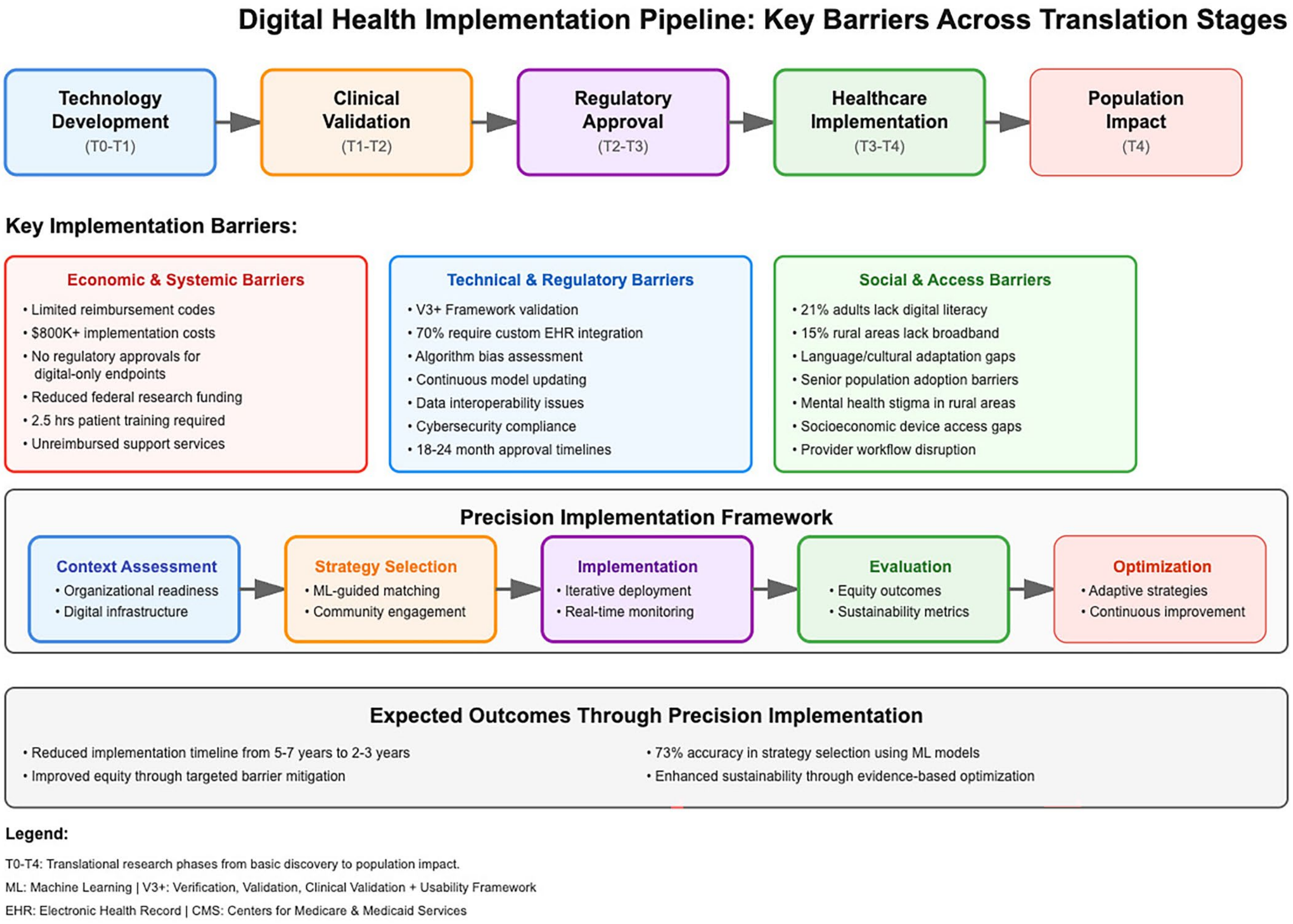

FIGURE 1 | Digital health implementation pipeline: From development to population impact with precision implementation framework.

validation requirements concentrate in early stages but create cascading effects throughout implementation. Social and access barriers, if unaddressed in early phases, can amplify during scaling, ultimately determining whether digital health innovations reduce or exacerbate health disparities. The precision implementation framework provides a systematic approach to identifying and mitigating these barriers based on contextual assessment rather than one-size-fits-all solutions.

Contemporary implementation science frameworks must also account for rapidly evolving regulatory requirements. The FDA's December 2023 final guidance on Digital Health Technologies for Remote Data Acquisition in Clinical Investigations established clear standards for verification, validation, and usability evaluation of digital tools in clinical research [7]. These requirements emphasize the importance of predetermined change control plans for adaptive algorithms, comprehensive data integrity measures, and robust evidence of clinical utility—elements that must be integrated into implementation strategies from the outset rather than addressed post-deployment.

5 | Toward Precision Implementation Strategies

The complexity and heterogeneity of implementation contexts suggest the need for more nuanced, tailored approaches to implementation strategy development. Just as precision medicine seeks to optimize therapeutic interventions based on individual patient characteristics, precision implementation approaches could customize implementation strategies based on contextual factors that influence adoption and sustainability.

Figure 1 illustrates how implementation barriers manifest across the translational pipeline from early technology development through population-level impact. The framework demonstrates that while FDA guidance on Digital Health Technologies for Remote Data Acquisition establishes comprehensive validation requirements—including verification, analytical validation, clinical validation, usability evaluation, predetermined change control plans, comprehensive data integrity measures, robust evidence of clinical utility, and ongoing post-market surveillance [4]—the associated costs and complexity represent significant implementation barriers, particularly for smaller organizations and academic institutions. Implementation of these extensive FDA requirements requires substantial financial investment plus specialized expertise that many healthcare organizations lack, effectively creating access barriers despite their intended facilitative role. Community frameworks like the Digital Medicine Society's V3+ provide additional standardization guidance but represent supplementary best practices rather than regulatory requirements.

This translational pipeline illustrates the progression from technology development (T0–T1) through population-level impact (T4), with implementation barriers categorized by type and stage. Economic/systemic barriers (red) include funding constraints and reimbursement gaps that persist across all stages. Technical/regulatory barriers (blue) represent compliance requirements and validation costs. Social/access barriers (green) reflect disparities that can widen without targeted intervention. The precision implementation framework (bottom) demonstrates how systematic barrier assessment and context-specific strategy selection can reduce implementation timelines while improving equity outcomes through evidence-based mitigation approaches.

Advanced analytical approaches are beginning to show promise for developing precision implementation strategies, though applications remain limited. For example, the FDA's 2024 AI/ML Action Plan updates provide specific frameworks for adaptive algorithms in clinical settings, including predetermined change control plans that enable continuous model refinement while maintaining regulatory oversight [3]. Recent implementation research has demonstrated that machine learning models can predict optimal implementation strategies with 73% accuracy when trained on organizational readiness assessments, staffing patterns, and technology infrastructure data from over 200 healthcare facilities [6]. However, the application of these approaches requires careful attention to algorithmic bias and equity considerations, as predictive models may inadvertently favor well-resourced healthcare systems and perpetuate existing disparities in digital health access.

Community-engaged research methods represent another component of precision implementation approaches. Meaningful engagement of patients, caregivers, healthcare providers, and community stakeholders throughout the implementation process could ensure that strategies are responsive to local needs, preferences, and constraints. This engagement appears particularly important for digital health interventions, where successful implementation often requires significant changes in care delivery patterns and patient behaviors. Table 1 provides an analysis of six major digital health technology categories, detailing their demonstrated achievements alongside specific implementation barriers, training requirements, and regulatory considerations that inform precision implementation strategy development.

6 | Contemporary Regulatory Framework for Digital Health Implementation

The aforementioned Digital Medicine Society's V3+ extension has emerged as the industry standard for evaluating sensor-based digital health technologies, extending the foundational V3 framework to include usability validation as a fourth critical component [8]. This framework includes: (1) verification, (2) analytical validation, and (3) clinical validation, with the recent addition of usability validation to ensure technologies meet user needs at scale. The V3+ extension addresses critical gaps identified in digital health implementation by incorporating the evaluation of user experience, human factors design, and real-world usability that traditional technical validation approaches often overlook [9].

However, significant regulatory science questions remain regarding post-market surveillance of adaptive digital health technologies and the development of streamlined pathways for iterative improvements. Unlike traditional medical devices, digital health tools can be updated continuously, requiring novel approaches to change management and ongoing safety monitoring [10]. The translational science community has an opportunity to inform evidence-based policy development by conducting

TABLE 1 | Digital health technology implementation barriers, training requirements, and regulatory status across four major technology categories.

Technology	Key achievements	Primary implementation barriers	Training requirements	Geographic/access limitations	Regulatory status
Telehealth platforms	• 85% adoption during COVID-19 • 78% patient satisfaction • $1200 average cost savings per encounter	• EHR integration complexity • Reimbursement gaps • Provider workflow disruption	• 2–4 h initial training • Monthly workflow updates	• Rural broadband gaps (15% lack access) • Urban–rural specialist access disparity	• CMS telehealth flexibilities extended through 2024 • State licensing reciprocity varies
Remote patient monitoring	• 35% reduction in hospital readmissions • 50% increase in medication compliance • Real-time physiological data collection	• Device interoperability issues • Patient compliance challenges • Alert fatigue among providers	• 1–2 h device setup • Weekly data review protocols	• Cellular connectivity requirements • Device shipping/return logistics	• FDA Class II device approval for most • CMS RPM codes available (99453–99,458)
AI-enabled diagnostics	• 94% accuracy in diabetic retinopathy • 15% improvement in radiology efficiency • FDA approval for 100+ algorithms	• Algorithm bias validation • Physician liability concerns • Integration with clinical workflows	• 10–20 h algorithm training • Continuous competency assessment	• Advanced computing infrastructure needed • Rural facility technology gaps	• FDA AI/ML guidance (2024) • Predetermined change control plans required
Wearable health devices	• 200+ million devices globally • 73% user satisfaction for fitness • Early cardiac arrhythmia detection	• Clinical vs. consumer-grade distinction • Workflow integration complexity • Regulatory pathway uncertainty	• Minimal for basic fitness • Clinical interpretation training	• Socioeconomic barriers to device access • Digital literacy requirements (21% adults lack skills)	• FDA clearance for medical claims • Consumer vs. medical device distinction

Note: This table synthesizes concrete examples of digital health achievements alongside specific implementation barriers, training requirements, geographic limitations, and regulatory considerations across four major technology categories. Data compiled from FDA approvals database, CMS reimbursement schedules, and peer-reviewed implementation studies published 2023–2025. Training hour estimates based on published implementation protocols and provider survey data.

research on these regulatory science questions and developing methodologies for continuous benefit–risk assessment of evolving digital health technologies.

They can support evidence-based optimization through focused regulatory science research on post-market surveillance methodologies, implementation outcomes studies that strengthen the evidence base for coverage decisions, and standardized approaches to algorithmic bias assessment. Recent developments like the FDA's Digital Health Technologies guidance and the Digital Medicine Society's V3+ Framework demonstrate the effectiveness of working within established pathways while addressing digital health-specific considerations. The goal should be regulatory clarity and optimization rather than regulatory proliferation.

7 | Implications for Translational Science

The digital health revolution presents both opportunities and challenges for healthcare equity and effectiveness. Whether these technologies ultimately improve or worsen health disparities may depend largely on how successfully the translational science community addresses implementation challenges.

Harmonizing existing frameworks represents a more practical approach than creating parallel regulatory structures. For example, integrating FDA device validation requirements with CMS health technology assessment criteria could create coherent pathways that leverage the strengths of each system while minimizing redundancy. This approach builds upon the proven foundation of current regulatory science while addressing digital health characteristics through targeted enhancements rather than wholesale replacement of established processes.

This suggests the value of sustained commitment to implementation science approaches that prioritize equity, community engagement, and contextual adaptation. It also points toward the need for methodological innovations that can capture the complexity of digital health implementation while providing actionable evidence for improvement. Perhaps most importantly, it indicates that successful digital health translation represents not merely a technical challenge but a fundamentally social and organizational transformation.

The translational science community has an opportunity to embrace this challenge with the same rigor and innovation that has characterized advances in basic biomedical research. Through such efforts, the promise of digital health technologies may be realized more equitably across all populations and communities.

Conflicts of Interest

The authors declare no conflicts of interest.

References

1. L. L. Zullig, C. Blue, M. J. Kelley, et al., “The Veterans Affairs Health Care System National Teleoncology Service: Veteran and Provider Perspectives and Experiences,” *Cancer Survivorship Research & Care* 2, no. 1 (2024): 2329363.

2. E. Proctor, H. Silmere, R. Raghavan, et al., “Outcomes for Implementation Research: Conceptual Distinctions, Measurement Challenges, and Research Agenda,” *Administration and Policy in Mental Health* 38, no. 2 (2011): 65–76.

3. Digital Medicine Society, “V3+ Framework: Extending Verification, Analytical Validation, and Clinical Validation to Include Usability Validation,” 2024, https://dimesociety.org/access-resources/extending-v3/.

4. Food and Drug Administration, “Digital Health Technologies for Remote Data Acquisition in Clinical Investigations: Guidance for Industry, Investigators, and Other Stakeholders. Final Guidance,” 2023.

5. J. C. Goldsack, A. Coravos, J. P. Bakker, et al., “Verification, Analytical Validation, and Clinical Validation (V3): The Foundation of Determining Fit-For-Purpose for Biometric Monitoring Technologies (BioMeTs),” *npj Digital Medicine* 3 (2020): 55.

6. AARDEX Group, ActiGraph, ATCOR Medical, et al., “Foundational V3 Framework Extended to Incorporate Usability Validation of Sensor-Based Digital Health Technologies. Digital Medicine Society Collaborative Community (DATAcc),” 2024.

7. M. Alsumidaie, “Unpacking FDA Guidance on Digital Health Technologies in Clinical Trials. Clinical Trial Vanguard,” 2024.

8. B. Abraham and K. Johnson, “The Evolution of Digital Health Policy: A 2024 Retrospective and 2025 Outlook,” EVERSANA Insights, 2025.

9. K. E. Trinkley, R. An, A. M. Maw, R. E. Glasgow, and R. C. Brownson, “Leveraging Artificial Intelligence to Advance Implementation Science: Potential Opportunities and Cautions,” *Implementation Science* 19, no. 1 (2024): 28.

10. R. Chen, K. Martinez, and Implementation Prediction Consortium, “Machine Learning Approaches for Implementation Strategy Optimization: A Multi-Site Validation Study,” *Implementation Science* 19, no. 1 (2024): 15.