Extended Reality in Clinical Medicine: Challenges from Prototype to Product

Navigating the complex landscape of XR medical device development through industry insights and translational strategies

Jennifer Reneker, PT, MSPT, PhD

Northeast Ohio Medical University

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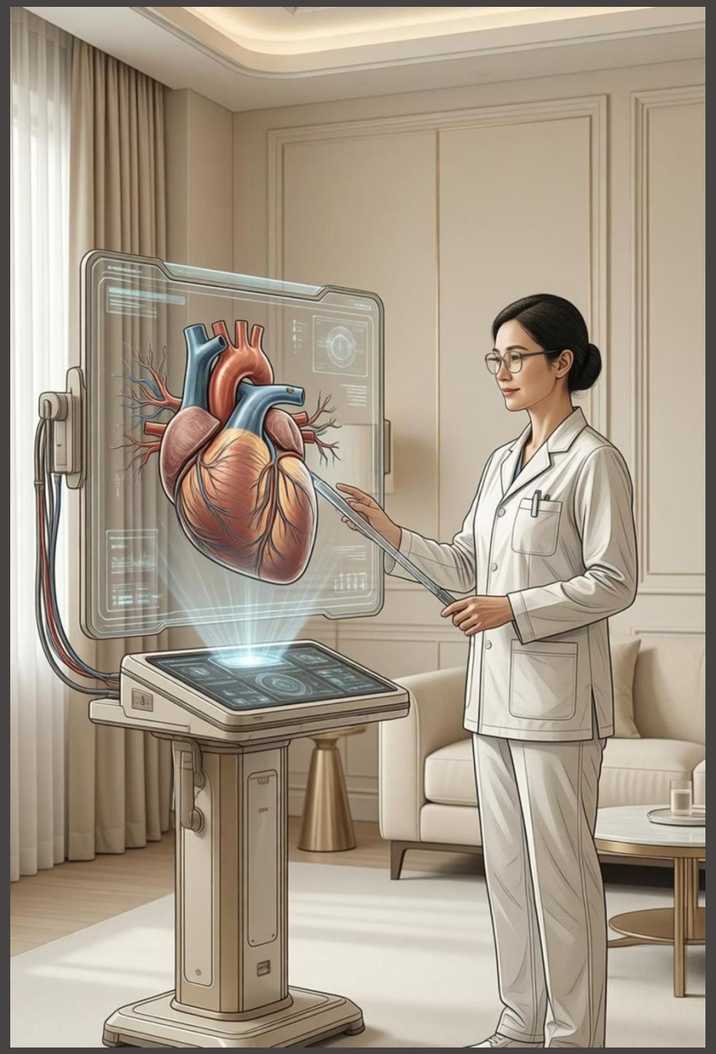
Clinical Applications Across Medical Domains



XR technologies are being applied across numerous clinical contexts, transforming traditional approaches to patient care and medical training:

- **Surgical Planning & Guidance:** Interactive 3D anatomical models and intraoperative visualization systems
- **Neurorehabilitation:** Motor function recovery following stroke or traumatic brain injury
- **Pain Management:** Immersive distraction therapy for procedural and chronic pain
- **Mental Health:** Exposure therapy, cognitive behavioral interventions, and anxiety reduction
- **Medical Education:** Simulation-based training for both clinicians and patients

Understanding Industry Challenges: Our Approach

To explore the experience of digital medicine innovators, we conducted interviews with XR healthcare companies worldwide to ask questions about their product lifecycle, funding, regulatory, reimbursement, and research.

01

Participant Recruitment

IVRHA Executive Director facilitated connections

02

Structured Interviews

30-minute one-on-one conversations

03

Summary Analysis

Independent review by multiple authors with AI-assisted thematic identification

Industry Landscape: Key Findings

21

Interviews

Representing mental health, rehabilitation, maternal health, surgical training, and patient education

7

Fully Commercialized

Only one-third achieved full market entry

15

Applied for Funding

Sought state or federal grant support

17

Report High Research Interest

16 Rate continued research efforts 10/10

Five Primary Challenge Categories

1. Human subjects research design and execution
2. Academic-industry partnerships and collaborations
3. Funding acquisition and sustainability
4. Commercialization and market strategies
5. Regulatory approval pathways

Navigating the Research Dilemma

17 of 21 companies rated continued research efforts as critically important. Despite this, few possessed peer-reviewed publications or concrete plans for high-quality research

Recognized Need

Companies understand research validates efficacy and supports commercialization

Critical Barriers

Limited research design expertise, No IRB access, Limited participant populations

Malalignment between researcher and company needs

Seeking Solutions

Academic collaboration is attractive but often fails to produce high impact results for the company

Academic-Industry Disconnect: Behind the Curtain

University Research Environment

Research-1 Institutions:

- Faculty must support salaries with external funding
- Strong infrastructure: IRBs, sponsored programs, clinical coordinators
- Expertise and participant access for rigorous trials
- *Require adequate funding to justify participation*

Teaching-Focused Institutions:

- Lower salary support requirements from grants
- Less robust research infrastructure and support
- Limited access to clinical populations
- *Faculty may engage without external funding for scholarly requirements*

Industry Collaboration Challenges

Investigator-Initiated Projects: Often fail to align with regulatory strategy or answer companies' burning questions.

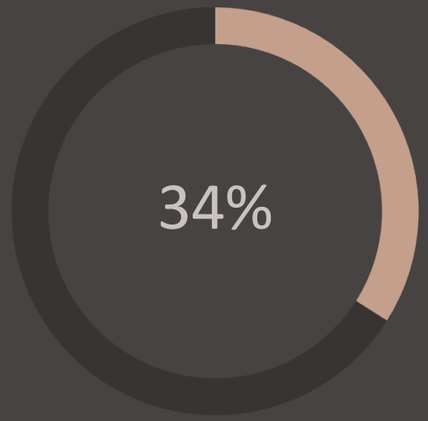
Failed Partnerships: Studies never completed or protracted study timelines—wasting time and equipment investments.

Misaligned Incentives: Researchers need justification for unpaid work. Companies need strategic, high-impact studies.

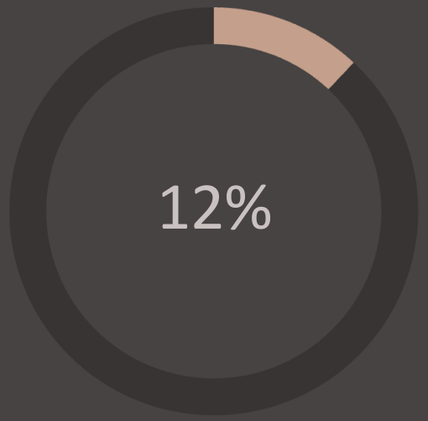
Creative Strategies for Limited Budgets: Partner with junior faculty establishing research lines, who may accept unfunded or partially funded studies. Consider in-kind equipment donations to early-career investigators building laboratory infrastructure.

CRITICAL BARRIER

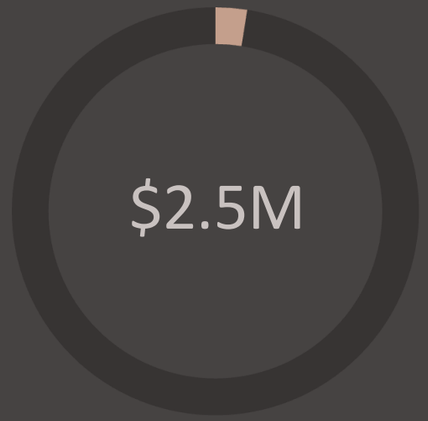
The Funding Crisis: No Margin – No Mission



SBIR Success Rate (2001)



SBIR Success Rate (2024)



Median Seed Round (2024)

Common Funding Sources

- Self-funding
- Seed rounds
- State grants
- Federal grants (limited success)

Federal Funding Reality

Success rates plummeted from 34% (2001) to just 12% (2024). One interviewee called the SBIR process a "waste of time."

Research Cost Shock

Clinical trials at research institutions can cost $41,413 per patient for pharmaceutical studies. Digital medicine startups should expect six- to seven-figure expenses for high-quality trials.

Grant Funding Challenges: Timing and Constraints

Specialized Skill Requirements

Grant writing takes years to master. Entrepreneurs building businesses lack time or incentive to develop this expertise, creating a significant capability gap.

Timeline Misalignment

Startups require rapid, flexible capital. Grant cycles delay progress for months—application windows, review periods, award decisions, and fund distribution—while business needs evolve.

Spending Restrictions

Grant funds come with usage restrictions. Pressing needs at application time may no longer be urgent when funds arrive. Startups need spending flexibility for rapidly shifting priorities.

The incentive challenge: Faculty need justification for front-end time investment in grant writing and study design—essentially betting on payoff if funding is secured.

Regulation and Revenue

The FDA Dilemma

Medical Device vs. Wellness Tool

Product Language Matters

Companies carefully craft messaging around "disorder management" and general wellness rather than diagnosis or treatment claims to stay outside regulatory scope.

Research Limitations

Self-exempt devices face barriers in clinical trial design. IRBs require detailed justification for regulatory status, potentially limiting study options and patient population research.

Policy Carveouts

Some categories, like video game-based physical therapy, operate under explicit FDA exemptions—but this freedom comes with trade-offs in commercialization pathways.

Revenue Model

Insurance Based

Providers bill using AMA-maintained codes. Adding new codes for digital therapeutics is expensive, lengthy, and uncertain.

Direct to Consumer

Companies must determine target population – Provider vs. Individual Consumer

Recommendation

A Multi-Institutional Consortium

01

Bridge Industry & Academia

Connect XR hardware/software vendors with clinical, translational, and regulatory research groups.

02

Shared Infrastructure

Leverage XR simulation facilities, and data-analytics platforms to reduce duplication and costs.

03

Consultancy Services

Short-term engagements for workflow evaluation, user-needs assessment, market analysis, and regulatory guidance