Biobusiness briefs

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Digital endpoints in clinical trials: building the business case for systematic adoption

Endpoints anchor clinical development. They define trial outcomes, determine regulatory approval and shape payer decision making.

Traditional endpoints often rely on infrequent, clinic-based assessments that are subjective and burdensome for patients. By contrast, digital endpoints — defined as trial endpoints derived from data captured by sensor-based digital health technologies — capture high-resolution, objective data during patients' everyday lives, creating opportunities to improve patient recruitment and retention, detect safety signals earlier and measure efficacy with greater sensitivity. Digital endpoints can reduce trial size, accelerate timelines and generate high-value insights for researchers, regulators, clinicians, patients and payers, including post-market evidence that supports label expansion and payer negotiations.

Digital endpoints are therefore a powerful lever to improve efficiency and effectiveness in drug development. However, the adoption of digital endpoints to date has been limited and uneven across the pharmaceutical industry owing to the perceived risks of their novelty.

Now though, regulators are signalling their readiness to consider regulatory applications including evidence of the effects of therapeutics on digital endpoints. FDA guidance on digital health technologies aligns with established evidentiary frameworks, such as V3+ (*npj Digit. Med.* **8**, 51; 2025), and encourages early sponsor engagement. Many technologies are mature and the regulatory pathway is open (*JAMA Health Forum* **6**, e250165; 2025).

Financial pressure on the pharmaceutical industry demands R&D innovation underpinned by a strong business case. By combining tangible proof points of the demonstrated impact of using digital endpoints with the business case, sponsors can build confidence, scale adoption and unlock the full value of digital endpoints across their drug development portfolios.

With the aim of informing such efforts, here we highlight the operational and financial impact that digital endpoints can have in clinical development, as well as cases where they have either been successfully used with realized benefit or evaluated with quantified potential future benefit, presented within a structured framework.

Business case for digital endpoints

The operational and financial impact of applying digital endpoints in drug development (Table 1) has recently been quantified for the first time (*Clin. Transl Sci.* **17**, e13902; 2024).

The analysis drew on 164 industry trials containing 393 digital endpoints, compared against a reference set of 11,466 industry-sponsored trials initiated from 2005 onwards. To reflect where digital endpoints are most frequently used today, the study focused on cardiovascular, central nervous system (CNS) and diabetes indications, which together account for about 70% of all digital endpoint deployments. In phase II and especially in phase III studies, these efficiencies translated into shorter cycle times and smaller enrolment requirements, enabling earlier go/no-go decisions and generating substantial financial returns. When considering the median implementation cost of a digital endpoint, the return on investment (ROI) for a phase III study is 14–22-fold, depending on therapeutic area, compared to a study without a digital endpoint (Table 1).

These results demonstrate measurable, repeatable and scalable value. Digital endpoints are already delivering, or expected to deliver, operational efficiencies and financial returns in active programmes today (Fig. 1).

Table 1 | Operational and financial impact of using digital endpoints by trial phase

Cost* (US$)	Operational effect	Change in eNPV	Return on investment
Phase II trials			
$1 million	Reductions in trial length (3–4 months) and size (11–16%)	$5.8–7.0 million	2.9×—3.5×
Phase III trials			
$1 million	Reductions in trial length (4–5 months) and size (12%)	$27.8–43.9 million	13.9×—21.9×

*The change in expected net present value (eNPV) and the return on investment values are based on the median digital endpoint implementation cost. See *Clin. Transl Sci.* **17**, e13902; 2024 for details.

Framework for systematic adoption

To capture measurable and repeatable returns, the adoption of digital endpoints must be systematic, integrated into portfolio strategy and taken to scale. The Digital Medicine Society (DiMe) Digital Endpoints Value Framework provides a structured approach to understanding where and how value is created across the drug development lifecycle.

Screening. Recruitment is one of the most important drivers of trial delays and cost overruns. Digital measures can streamline this step by enabling remote pre-screening to identify eligible participants more efficiently and design more patient-centric and engaging studies, and by enriching trial populations through objective, real-world data. This not only reduces timelines and costs but also broadens access to more representative patient groups.

For example, in Alzheimer's disease, a model evaluating the integration of digital and plasma-based pre-screening approaches indicated the potential for substantial reductions in recruitment timelines and overall trial costs by identifying eligible participants earlier in the process.

Safety. Digital endpoints allow continuous safety monitoring, capturing subtle, transient or cumulative adverse events that may be missed with intermittent, clinic-based assessments. Earlier detection protects participants, supports faster resolution of adverse

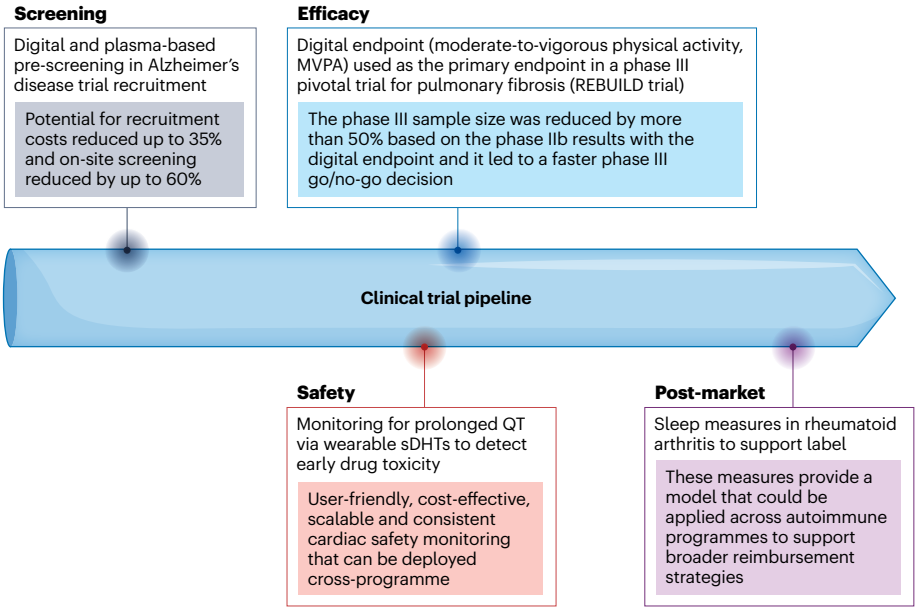


Fig. 1 | Applications of digital biomarkers in clinical trials. For further details, see the text and the Digital Endpoints Value Framework. sDHTs, sensor-based digital health technologies.

events and builds stronger safety packages for regulators.

For example, wearable-based QT interval monitoring has demonstrated the ability to identify cardiac safety risks earlier and more consistently than traditional clinic-based ECG assessments (*Front. Cardiovasc. Med.* **10**, 1172666; 2023).

Efficacy. Digital measures can improve sensitivity and precision, reducing variability and enabling detection of treatment effects sooner. These qualities can translate into smaller sample sizes and shorter trial durations. For phase II trials, this means earlier go/no-go decisions and better resource allocation. For phase III trials, it drives multi-million-dollar gains in estimated net present value (NPV) while maintaining evidentiary rigour.

For example, in the phase II trial of a pulsatile nitric oxide delivery system for the treatment of fibrotic interstitial lung disease, accelerometer-derived measures of moderate-to-vigorous physical activity (MVPA) showed a stronger signal of functional improvements than traditional endpoints. MVPA was used as the primary endpoint in the phase III trial, which enabled a smaller study and faster decision-making.

Post-market. Beyond initial approval, digital endpoints provide ongoing real-world insights. They can uncover additional therapeutic benefits, support label expansion and inform payer negotiations.

For example, in rheumatoid arthritis digitally captured sleep metrics may objectively and conveniently detect meaningful improvements that could provide evidence to support label claims and strengthen reimbursement cases (*Digit. Biomark.* **5**, 191–205; 2021).

Industry implications

The ROI case for digital endpoints is becoming increasingly well established. Underinvestment now represents a missed opportunity.

Systematic adoption can strengthen R&D efficiency, reduce operational risk, enhance regulatory engagement and improve the payer value proposition. Cross-programme strategies allow validated endpoints to be reused and harmonized, reducing implementation costs and accelerating regulatory familiarity. Precompetitive collaboration expands these benefits, creating shared standards that reduce duplication across the industry. Sponsors that view digital endpoints as a portfolio-level investment will be best positioned to capture efficiencies, mitigate risk and deliver sustained financial returns.

Progress has been hindered by a stalemate. Industry argues that large-scale adoption cannot occur without regulatory certainty. Regulators cannot offer much more insight until further high-quality examples are submitted. Breaking this cycle requires leadership from sponsors.

Digital endpoints are proven value drivers with quantifiable returns. The decision is whether to wait and risk being constrained by legacy methods for fear of failure in an industry already characterized by a 95% technical failure rate, or to lead. Early movers who invest in digital endpoints, set standards and share evidence will not only capture the greater financial reruns, but will also shape the regulatory and evidentiary landscape of the future.

Jennifer C. Goldsack[1] ✉, **Sarah Ernst**[2], **Marissa F. Dockendorf**[3], **Thanneer M. Perumal**[4] & **Benjamin Vandendriessche**[1,5]

[1]Digital Medicine Society (DiMe), Boston, MA, USA. [2]Sanofi, Morristown, NJ, USA. [3]Merck, Rahway, NJ, USA. [4]F. Hoffman-La Roche, Basel, Switzerland. [5]Case Western Reserve University, Cleveland, OH, USA.
✉e-mail: jennifer@dimesociety.org

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Competing interests

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Additional information

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