



The 3Ps of
Digital Endpoint Value
PATIENTS · PHARMA · PAYERS

Opportunities and challenges to using digital clinical measures to inform reimbursement decisions in drug development

Excerpt from [Using evidence from digital endpoints to demonstrate the value of a new drug: Considerations and recommendations](#) / Appendix 2

The value of digital endpoints for reimbursement decisions

To date, digital clinical measures have primarily been developed for evidence generation in clinical development. For example, as endpoints for decision making during drug development and in anticipation of supporting registration of new drugs and other medical products.

Digital endpoints can capture high quality, high resolution data, including information about new facets of disease that have been previously impossible to measure, with little patient burden. As such, it is critical that pharma, payers, and patients intentionally plan for including such evidence in value and reimbursement discussions.

The value that digital endpoints offer to reimbursing and pricing decisions:

1. Digital endpoints are delivering **high quality evidence** across a range of therapeutic areas:
 - Clinical - tracking symptoms and exacerbations
 - Humanistic - Health Related Quality of Life (HRQoL), independence, activities of daily living
 - Economic - hospitalizations, readmissions, preventable increase in acuity
 - Risk reduction - predictive applications and stratification

2. Digital endpoints can support a **more complete** understanding of **patients' lived experience**: This includes the capabilities to:
 - Better measure, and in turn manage, daily fluctuations or cyclical changes in symptoms
 - Improve early detection
 - Lower the burden of assessment, often through passive data collection

“No one understands my disease until they measure me at my best and at my worst: the best is the potential, and the worst is the opportunity”

- *Patient Expert*

“We are not introducing new measures because we can, but rather because they capture something new and relevant”

- *Pharma Exec*

Patient stakeholders underlined the opportunity for “dual-use” of evidence: evidence as an outcome and as feedback to patients to support outcome improvement. This points to a further source of value:

3. **Evidence** for all ‘3Ps’: **Pharma, payers** and **patients**. Digital clinical measures can provide valuable information to patients directly in addition to sponsors and reimbursement committees. Patients recognize the opportunity for outcome improvements by using digitally generated data to:
 - Plan and manage their day
 - Understand the benefits of treatment
 - Set goals and manage expectations
 - Communicate their symptoms to clinicians and caregivers
 - Provide more relevant information

Our findings and [existing evidence](#) informs us that patients are very open to sharing data if it returns value to them through **better, more affordable** care.

Digital clinical measures can support value-based care models

Value based care require hard outcomes data, which can be more readily captured using digital clinical measures. Further opportunities for capturing evidence of value are possible when it is possible to treatment benefit for each individual patient.

1. **Early signals** captured with **high resolution** and **low patient and provider burden**.
 - Digital clinical measures can enable high resolution, predictive or prognostic measures that provide high quality

With traditional tools, measuring outcomes that are predictive of future clinical state is often extremely burdensome to patients, often requiring a high degree of repetition and unclear value for the patient.

“Why keep asking me to come to the

indicators of hard clinical outcomes such as hospitalization.

clinic to draw a circle when I couldn't do it the last time?"

- Patient Expert

2. More **complete** insights into the **patient experience**.

- Currently, most measures are captured only sporadically, reflecting little of the daily lived experience of patients and missing short term symptom fluctuations.

The [Integrated Alzheimer's Disease Rating Scale \(iADRS\)](#) combines digital tools and long term clinical outcomes into a single outcome assessment. This adapted scale also includes long term changes relevant to patients with Alzheimer's disease and to payers.

3. **Personalized** definitions of **value** and **benefit**

- Digital clinical measures can demonstrate benefit on an individual patient basis.

Enabled by profiling ability, personalized treatment regimes already exist in oncology. These personalized approaches have helped inform reimbursement decisions, but have required [time and investment](#).

Technical and systematic challenges are inhibiting the use of digital endpoint data in value and reimbursement discussions

1. Data heterogeneity.

- **Interpreting** the data generated by digital endpoints is **more challenging** when data is captured in the **real-world**, outside of the highly controlled clinical trials environment and with less information on possible confounders.

2. Confusion and knowledge gaps.

- Currently, there is **widespread confusion** about what digital clinical measures are and what **value** they bring. For example, digital clinical measures that generate evidence in support of the performance of traditional medical products are often confused and/or conflated with digital medical products
- Key stakeholders in reimbursement decisions, such as members reimbursement committees and actuaries, must be supported in **learning** and **active engagement** with this important topic.

3. Data availability.

- Even when a digital endpoint is acceptable to payers, it may not yet be feasible to collect this evidence at scale in a general population.

- Translation of digital clinical measures from use as endpoints in clinical trials to use as screening, monitoring, and diagnostic tools in routine clinical care is critical to generating high-quality digital data in real-world settings.
4. Generalizability of knowledge.
- Currently, there is insufficient knowledge about how culture, socioeconomic status or language barriers impact acceptance and use of digital clinical measures.
 - Measuring the value of a treatment for every patient means that digital clinical measures requires must be used by every patient. More research is needed to establish best practices to ensure that digital clinical measurement is acceptable to everyone.
5. Scaling digital data collection.
- Digital clinical measures offer a low-burden, cost effective way to capture baseline and population-level data to use as comparator data. However, widespread monitoring requires broad trust and consent, which must first be earned through robust advances in privacy, security and infrastructure.