Decision tool for integrating digital endpoint evidence into your Integrated Evidence Plan

Are you considering including digital endpoints in your IEP?

NO → Review DiMe best practices resources on how digital endpoints could add to value and reimbursement discussions

[Key opportunities](#) include: Generating **high quality evidence**, that helps reach a **more complete understanding of the lived experience** and helps **link behaviors to long-term outcomes**

YES ↓

Have you already engaged with payers to discuss acceptability of digital endpoint evidence?

NO → Early engagement with payers, as key stakeholders in bringing new products to market, is critical! Engagement can be in parallel with regulatory interactions.

YES ↓

Are there broadly accepted digital endpoints in your setting/ indication of interest?

NO → As you develop / advance broadly accepted digital endpoints, consider the following to increase acceptability to payers:

1. Validate and [evaluate](#) versus HRQoL and patient-centric outcomes as well as established clinical outcomes
2. Invest early in studies trying to assess long term outcomes and events
3. Include study design elements that allow for estimation of Minimal Clinically Important Difference (MCID) on an individual level
4. The relevance of the digital endpoint across individuals and over time
5. Demonstrating absence of any bias in how the endpoint is measured and adopted

YES ↓

Have the digital endpoints been previously accepted by payers?

NO → Looks like you can move to deployment of the digital endpoint in a pivotal trial. Here are some points to think about:

1. Prioritize collection of confirmatory evidence that shows scalability of new evidence
2. Include outcomes that matter to payers in trials (e.g. medical cost usage, hospitalization), for example by collecting more RWE, in parallel with digital DDTs
3. Engage early with [NQF and NQVA](#) as well as payers and regulators

YES ↓

Congratulations! You are in a great position to include patient-centric digital endpoint evidence in your IEP!

Access the [full suite of resources](#) on the DiMe website

Who is this tool for? Pharmaceutical companies developing new drugs and other medical products evaluated using data derived from digital endpoints. A secondary audience is vendors developing digital clinical measures for use as digital endpoints in trials of new drugs and other medical products.

When should they use it? As early as possible in the Integrated Development Plan (IEP) development process, or ideally, even earlier in the product lifecycle (e.g. in early clinical development).

What is it for? This tool will help you decide if there is an opportunity to include digital endpoints in your IEP, and if so how to go about it.

What Is An Integrated Evidence Plan?

An Integrated Evidence Plan (IEP) are [processes and documents which create a robust strategy connecting labeling concepts and goals for the new product to the development strategy and the evidence-generating trials and studies in the program](#).

Building off previously generated data, the IEP focuses on evidence that needs to be generated to advance stakeholder decision-making. The IEP "[defines how the evidence will be generated within each clinical trial and real-world observational study, and how this will be leveraged to satisfy patient, physician, provider, payer, and regulatory requirements as defined](#)."

Although IEPs look slightly different from company to company, they all aim to [increase productivity by helping companies plan for and assess the likelihood of getting a product to market](#). IEPs also include criteria for terminating programs if evidence requirements are not met, mitigation plans and strategies for expansion, if appropriate.

3P

DiME DIGITAL MEDICINE SOCIETY

The 3Ps of Digital Endpoint Value

PATIENTS • PHARMA • PAYERS