



The 3Ps of Digital Endpoint Value

PATIENTS · PHARMA · PAYERS

Recommendations for pharma

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

These recommendations are intended to help pharma stakeholders advance the acceptability of evidence derived from digital endpoints for payers.

Best practices throughout the drug development process

1. Engage with payers alongside regulators as soon as the decision to include a digital endpoint is made
2. Prepare to bridge knowledge gaps and requirements to demonstrate acceptability and value of digital endpoints to all stakeholders
3. Build your IEP before starting your clinical trials

Repeatedly the payer stakeholders stressed the need for engagement with the different payer bodies in trial design, even in tool ideation phases to ensure that their perspective is heard and included. “Early and repeated payer interaction is the path forward if you want to change things.”

- *National Payer*

To assist stakeholders from pharmaceutical and other companies who are developing new DDTs, drugs or medical products, the project team has developed this [decision guide](#) to facilitate inclusion of relevant, acceptable and informative digital endpoints into integrated evidence plans.

Recommendations during digital endpoint selection and development

1. Validate and [evaluate](#) digital endpoints against health-related quality of life (HRQoL) and patient-centric outcomes and patient reported outcomes (PROs) as well as established clinical outcomes
2. Investigate the relationship between digital measures and endpoints with long term outcomes and events

3. Include study design elements that allow for estimation of minimal clinically important difference (MCID).
4. Engage early with national healthcare standards bodies such as the [National Quality Forum \(NQF\)](#) in the US, as well as payers and regulators, to advance acceptance of the digital endpoint.
5. Develop evidence of acceptability and usefulness of a new measurement outside of clinical development.

“To ensure full acceptability of the new measure, digital or not, it is essential to develop the tool with a high level of consensus between the different stakeholders; patients, subject matter experts (SMEs), regulators, payers etc. Validation is of less importance if the acceptability and appropriateness of the new tool is secured.”

- *National Payer*

6. Select endpoint(s) that are scalable for collecting evidence in the real world and fit-for-purpose across individuals and over time to account for the progression of disease and individual experiences.
 - For example, developing a suite of measures, ideally from a single digital measurement product, that is relevant across the patient experience (e.g. pre- and post- events, or different disease phases) and across individuals, or efforts to establish core measure sets for patient relevant measures (e.g. ambulation).

Recommendations during digital endpoint deployment

1. Prioritize collection of confirmatory evidence that shows scalability of new evidence as well as the relationship to accepted endpoints in clinical development (e.g. a real world equivalent of the six minute walk test)
2. Include outcomes that matter to payers in trials (e.g. medical cost usage, hospitalization)
3. Collect more real-world evidence (RWE), in parallel with digital endpoints, earlier in clinical development