Recommendations for payers

Excerpt from Using evidence from digital endpoints to demonstrate the value of a new drug: Considerations and recommendations / Recommendations for payers

1. Align as an industry to provide consistent guidance to pharma and their partners developing and deploying digital endpoints on topics including
   ○ Evidence thresholds for acceptability of a digital endpoint in a given context, digital endpoint validation, and MCID
   ○ Appropriate instruments to use as comparators (e.g. for HRQoL)

2. Define pathways for pharma to engage with you early in their IEP development

3. Align further with regulatory decision-makers wherever possible to streamline the evidence generation process for digital endpoints and the new drugs they are evaluating.

Recent progress and existing efforts to align payer and regulatory decision-making are extremely valuable and encouraging.

- In the EU, the HTA-EMA collaboration includes the development of a parallel consultation process
- In the US, the Payor Communication Task Force aims to accelerate patient access to medical devices.
  - While there are still challenges remaining, successes have been achieved

Examples of misalignment across regulatory and payer decisions include

- Decisions related to aducanumab (Aduhelm) for the treatment of Alzheimer’s disease
- Relevance of FEV1 as a measure in COPD

4. Consider the opportunity to encourage more personalized treatment regimes, for example by providing guidance on using digital endpoints to define treatable traits and benefits for individuals

Access the full resources on the DiMe website