The 3Ps of Digital Endpoint Value

PATIENTS · PHARMA · PAYERS

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