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DIGITAL BYTES

A monthly byte into the latest digital health solutions news

Digital health technologies document outlines framework for FDA

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At the end of March, the FDA released a framework to address the long-standing questions on the use of digital health technologies (DHTs) in clinical drug trials. The framework focuses on the data derived from DHTs during clinical investigations, which has historically been limited and unclear. The FDA highlighted the potential advantage of allowing digital technologies to aid in drug development, such as the innate ability to obtain clinical data from remote study participants and make continuous measurements of clinical features. This may reduce the burden on trial participants and potentially result in higher study enrollment and retention rates.

Though not an official guidance document, this roadmap is one step closer in the FDA's commitment to clarify its stance on the value of DHT. Before the end of the year, we expect further draft guidances from the FDA that reflect the agency's thinking on digital health solutions.

Click here to read the full article.

THE PAYER PERSPECTIVE:

- **Enhanced consistency for DHT development, use, and review will enable payers to develop more standardized review processes for clinical drugs**
- **An established steering committee of key stakeholders from various FDA divisions may foster shared decision-making and consistent reviewing approaches, supporting payers to make expedited coverage decisions**
- **Greater standardization of DHTs within clinical trials is promising, and could mean increased clarity when making future regulatory decisions about the coverage, reimbursement, and overall assessment of broader digital health solutions**

Click to view the framework in its entirety

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