FDA Aims to Accelerate Data Modernization Through TMAP

Data can accelerate the approval processes for new drugs and medical devices.

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The Food and Drug Administration is looking to modernize its internal technology infrastructure and the ways it uses data in regulatory processes through its Technology Modernization Action Plan (TMAP).
Released last September, the goal of the plan is to “make sense of all of their data in efficient ways so they can aggregate critical and sensitive information across different drug applications and medical device applications,” said FDA Principal Deputy Director and Acting CIO Amy Abernethy at last week’s Health Datapalooza in Bethesda, Maryland.

The main question FDA and other federal agencies have been looking to tackle, she explained, is how to modernize data, and part of that involves moving away from paper to more structured ways of managing and analyzing data.

“Just a decade ago, most drug applications came in paper,” Abernethy said, adding that there are still product applications that are still submitted by paper today. The agency is working to structure its digital documents, or unstructured PDFs, to accelerate approval and security interface processes.

Moreover, moving data into the agency efficiently requires three parts laid out by TMAP, she explained. This includes focusing on a cloud-forward infrastructure, creating an innovation space where real use cases can be applied, and opening communications to a larger community of data and tech innovators.

FDA will work with the overall community of data holders as well as researchers to understand what data fits their purposes for regulatory decisions, while new guidance documents will be issued to support the use of real-world evidence in these processes following the 21st Century Cures Act, she added.

This includes using real-world evidence pulled from non-traditional approval sources, such as electronic health records, wearable devices, insurance claims and social media, to accelerate approval processes.

FDA will hold a public meeting March 27 to identify an enterprise-wide strategy going forward in terms of data quality, privacy, data aggregation and data utilization.

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