FDA Qualifies First AI Tool for MASH Clinical Trials

AIM-NASH system could help standardize liver disease assessment and reduce the time and resources needed for MASH drug development.

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FDA Qualifies First AI Drug Development Tool, Will Be Used in MASH Clinical Trials

The U.S. Food and Drug Administration (FDA) has qualified the first AI drug development tool, the AI-Based Histologic Measurement of NASH (AIM-NASH), to help pathologists assess metabolic dysfunction-associated steatohepatitis (MASH) disease activity in clinical trials.

This cloud-based tool helps pathologists score liver biopsy components, including fat infiltration (steatosis), inflammation (hepatocellular ballooning and lobular inflammation), and scarring (fibrosis) stage.

MASH, a significant public health challenge affecting millions of Americans, is a severe form of metabolic-associated fatty liver disease [MASLD] that develops when fat buildup in the liver causes inflammation and scarring. MASH can lead to cirrhosis (severe liver scarring), hepatic decompensation (worsening of liver function), liver cancer, liver transplantation, or death.

Currently in MASH clinical trials, multiple experts independently assess liver histology, a time-consuming process made complicated by variable scoring. AIM-NASH could help standardize histologic assessment and reduce the time and resources needed for MASH drug development.

The AIM-NASH system uses AI algorithms to analyze images of liver biopsies and provides scores according to the NASH Clinical Research Network scoring system. The process keeps humans involved, as pathologists are fully responsible for final interpretation, reviewing the whole slide image and AIM-NASH outputs before accepting or rejecting the AI-generated scores.

The qualification was based on comprehensive validation studies demonstrating that AIM-NASH-assisted comparisons to expert consensus were similar to individual pathologists' comparisons to expert consensus.

Drug development tools play an important role in bringing new therapies to patients by providing well-defined, scientifically sound approaches to the conduct of clinical trials. Learn more about

FDA’s Drug Development Tools Qualification Programs here.

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