

# EU health regulator clears use of AI tool in fatty liver disease trials

The condition, called metabolic dysfunction-associated steatohepatitis, or MASH, is a difficult-to-treat disease that affects around 1.5 per cent to 6.5 per cent of adults in the U.S., according to the American Liver Foundation.



Bengaluru: A European Medicines Agency committee, on Thursday, accepted the use of an artificial intelligence (AI) tool called AIM-NASH in clinical trials to help identify the severity of a type of fatty

liver disease.

The condition, called metabolic dysfunction-associated steatohepatitis, or MASH, is a difficult-to-treat disease that affects around 1.5 per cent to 6.5 per cent of adults in the U.S., according to the American Liver Foundation.

The AI-based AIM-NASH tool employs a machine learning model trained on more than 100,000 annotations from 59 pathologists who assessed over 5,000 liver biopsies across nine large clinical trials.

The EMA's human medicines committee (CHMP) said evidence showed the AI tool can reliably determine disease activity from biopsies with less variability than the current standard in trials that rely on a consensus of three pathologists.

On that basis, the CHMP concluded, it can accept evidence generated by the tool as scientifically valid, which will help researchers obtain clearer evidence on the benefits of new treatments in clinical trials.

Drugmakers such as Novo Nordisk and Eli Lilly are also conducting trials with their blockbuster GLP-1 treatments to treat patients with the liver disease. (Reporting by Christy Santhosh in Bengaluru; Editing by Savio D'Souza)

**News Source:**

<https://pharma.economictimes.indiatimes.com/news/regulatory-update/eu-health-regulator-clears-use-of-ai-tool-in-fatty-liver-disease-trials/119258798>