

LITMUS - Liver Investigation: Testing Marker Utility in Steatohepatitis

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Strongly associated with the epidemics of obesity and type 2 diabetes that are testing healthcare systems worldwide, Non-Alcoholic Fatty Liver Disease (NAFLD) is an increasingly common cause of advanced liver disease that is characterized by substantial inter-patient variability in severity and rate of progression. It is currently assessed by liver biopsy, an invasive, costly and risky procedure.

The lack of noninvasive biomarkers has hampered patient care and impeded drug development by complicating conduct of clinical trials.

The overarching aim of LITMUS is to develop, robustly validate and advance towards regulatory qualification biomarkers that diagnose, risk stratify and/or monitor NAFLD/NASH progression and fibrosis stage.

This will be achieved through a goal-oriented, tri-partite collaboration delivering a definitive and impartial evaluation platform for biomarkers, bringing together:

- (i) End-users of biomarker technologies (clinicians with expertise in NAFLD and the pharmaceutical industry)?
- (ii) Independent academics with expertise in the evaluation of medical test/biomarker performance?
- (iii) Biomarker researchers and developers (academic or commercial).

LITMUS has the demonstrable capability to fulfil the IMI call remit. Built upon foundations laid by the Eufunded FLIP/EPoS projects and long-established, successful scientific collaborations amongst many of Europe's leading clinical-academic centres, LITMUS is at a unique advantage due to its existing large-scale patient cohorts, bioresources and multi-omics datasets.

Consortium members are internationally recognised experts with substantial relevant expertise supporting the program's clear focus on biomarker identification, validation and accelerating EMA/FDA qualification. Thus, LITMUS is powered to provide clarity on biomarker validity for NAFLD at scale and pace: supporting drug development and the targeting of medical care and limited healthcare resources to those at greatest need.

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