# Real-world identification, staging, monitoring, management, and progression in patients with metabolic dysfunction-associated steatohepatitis (MASH) across the fibrosis spectrum in EU4+UK: A retrospective multi-country chart review on compensated MASH cirrhosis (MASH-MAP)

**First published:** 20/10/2026

**Last updated:** 26/10/2026

Study Planned

## Administrative details

**EU PAS number**

EUPAS1000001142

**Study ID**

1000001142

**DARWIN EU® study**

No

**Study countries**

France

Germany

Italy

Spain

United Kingdom

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**Study description**

Metabolic dysfunction-associated steatohepatitis (MASH) is a long-term liver disease linked to metabolic conditions such as obesity and diabetes. It can cause inflammation and increasing liver scarring (fibrosis), which may eventually lead to cirrhosis, liver failure, liver cancer, or death. However, there is limited information on how people with MASH are identified, assessed, monitored, and treated in everyday clinical practice, particularly those with cirrhosis who have not yet developed serious complications.

This study will review existing medical records from approximately 750 adults with MASH receiving care across approximately 60 hospitals and clinics that provide specialist care for liver disease in Germany, the United Kingdom, France, Italy, and Spain. No new treatments, tests, or study visits will be given as part of the research.

The study will examine how physicians diagnose MASH and determine the amount of liver scarring (fibrosis staging) using blood-based tests, scans, liver biopsy, and other clinical information. It will also describe how patients are monitored and treated, how care differs according to the severity of liver scarring, and how often patients progress to more advanced disease. Particular attention will be given to patients with cirrhosis who have not yet developed complications.

The study will also explore whether information routinely recorded in medical records, such as diagnoses, procedures, medicines, and healthcare use, could help to identify patients with MASH-related cirrhosis in future research databases.

The findings are expected to improve understanding of how MASH is managed in routine European clinical practice and where there may be opportunities to improve disease identification, monitoring, and care.

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**Study status**

Planned

# Research institutions and networks

## Institutions

### GIPAM GmbH

Germany

United Kingdom

United States

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**Institution** **Other** **ENCePP partner**

# Contact details

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## Study timelines

**Date when funding contract was signed**

Actual: 26/03/2026

**Study start date**

Planned: 01/12/2026

**Data analysis start date**

Planned: 01/07/2027

**Date of final study report**

Planned: 31/03/2028

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

This study is funded by Madrigal Pharmaceuticals, Inc., the study sponsor. Funding covers research activities undertaken by the research team and participating study sites, including project management, investigator and research staff time, local identification of eligible patients and abstraction of relevant information from medical charts, data management, statistical analysis, and administrative costs associated with study conduct.

## Study protocol

MGL_OBS_MA_010_Madrigal_MCR MASH F4c EU4pUK_Protocol_v1_29SEP2026 - redacted.pdf (266.7 KB)

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Other study registration identification numbers and links

MGL_OBS_MA_010

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Study design:**

This is a retrospective, multi-country, multi-site, non-interventional chart review of adults with MASLD/MASH across fibrosis stages. Existing records are reviewed once per patient, with no patient contact or study procedures. Data cover pre- and post-index periods and are analysed descriptively.

**Main study objective:**

The primary objectives of this study are to:

1. Describe how patients with MASLD/MASH and compensated liver cirrhosis are identified and staged in routine clinical practice, including the use and sequencing of non-invasive liver disease assessments, imaging, liver biopsy, and other relevant clinical documentation;
2. Characterize real-world surveillance, care coordination, and therapeutic management patterns for patients with MASH across the fibrosis spectrum; and
3. Describe and compare demographic, comorbidity, and clinical characteristics across patients with non-cirrhotic liver disease (F0–F3), compensated liver cirrhosis, and decompensated liver cirrhosis.

## Study Design

**Non-interventional study design**

Cohort

# Study drug and medical condition

**Medical condition to be studied**

Metabolic dysfunction-associated steatohepatitis

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**Additional medical condition(s)**

Metabolic dysfunction-associated steatotic liver disease (MASLD)

# Population studied

**Short description of the study population**

The study population will consist of adult patients with MASLD and/or MASH (inclusive of historical nomenclature NAFLD and NASH) receiving care at participating hepatology and gastroenterology sites in France, Germany, Italy, Spain, and the United Kingdom.

Patients will be identified from routine medical charts available at participating sites and included based on documented clinical information sufficient to support fibrosis-stage classification and assessment of study variables relevant to the research objectives.

The study will include patients across three main fibrosis-stage cohorts:

1) non-cirrhotic liver disease (F0–F3),

2) compensated liver cirrhosis, and

3) decompensated liver cirrhosis.

Cohort assignment will be based on documentation available in the medical

chart, including staging information, non-invasive liver disease assessment results, imaging findings, liver biopsy results, and documentation of decompensation events.
The primary population of interest is patients with compensated MASH cirrhosis.

To support the study objectives, the population is intended to include patients representing different stages of disease severity and clinical management. This cohort structure will enable descriptive and comparative analyses across the three main fibrosis-stage groups, as well as assessment of progression across fibrosis stages.
Patients will be included only if adequate retrospective chart information is available to support evaluation of key study parameters within the predefined observation period.

The index date will be defined as the date on which a patient first meets the criteria for the assigned study cohort within the predefined cohort entry period.
Patients will be eligible for inclusion in the study if they meet all of the following criteria:
1. Documented, confirmed diagnosis of MASH/MASLD in the medical chart (including historical documentation using the term NASH, where applicable);
2. Index date within the predefined cohort entry period, with the earliest eligible index date being 01 January 2022 and the latest eligible index date defined to ensure a minimum of 12 months of post-index observation. Cohort assignment will be based on chart-documented clinical information, with the date on which the patient first meets the criteria for the assigned study cohort will be considered the index date, namely: non-cirrhotic (F0-F3), compensated cirrhosis, or decompensated cirrhosis;
3. Availability of ≥24 months of observable baseline history and ≥12 months of post-index follow-up, unless death occurs earlier; and

4. Age ≥18 years at the index date.

Patients will be excluded from the study if they meet any of the following criteria:
1. Evidence of alternate chronic liver disease etiologies inconsistent with MASLD/MASH definitions, including but not limited to alcohol-associated liver disease, viral hepatitis (e.g., hepatitis B or C), autoimmune hepatitis, primary biliary cholangitis, primary sclerosing cholangitis, Wilson’s disease, hemochromatosis, alpha-1 antitrypsin deficiency, glycogen storage diseases, and other metabolic or cholestatic liver diseases;
2. Evidence of heavy alcohol use or alcohol use disorder, including other alcohol-related diagnoses (e.g., alcoholic pancreatitis), drug-induced liver disease;
3. History of liver transplant prior to or on index;
4. Hepatocellular carcinoma prior to or on index; or
5. Insufficient medical chart documentation to support reliable cohort assignment or abstraction of key study variables; or
6. Participation in an interventional clinical trial at any time during the pre-index period, inclusion, and follow-up period.

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**Age groups**

- **Adult and elderly population (≥18 years)**

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**Special population of interest, other**

Adult patients with compensated MASH cirrhosis

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**Estimated number of subjects**

750

## Study design details

**Setting**

This is a retrospective, multi-country, multisite, non-interventional medical chart review conducted at approximately 60 hepatology and gastroenterology sites in France, Germany, Italy, Spain and the United Kingdom.

The study population comprises adults (≥18 years) with documented MASH/MASLD receiving routine clinical care at participating sites. Patients must have a confirmed MASH/MASLD diagnosis, qualifying fibrosis-stage documentation during the cohort entry period, and generally at least 24 months of observable pre-index history and 12 months of post-index follow-up, unless death occurs earlier. Patients will be excluded if another liver disease is primarily responsible for their condition, if relevant alcohol/drug misuse precludes MASH/MASLD classification, or if they had liver transplantation or hepatocellular carcinoma before/on index, insufficient chart documentation, or participation in an interventional clinical trial during the observation period.

The earliest eligible index date is 1 January 2022. The latest index date will be set at least 12 months before data abstraction to allow sufficient follow-up.

Study cohorts are classified according to the documented stage of liver disease: non-cirrhotic liver disease (F0–F3), compensated liver cirrhosis, and decompensated liver cirrhosis. Where sufficient detail is available, non-cirrhotic patients will be further grouped as F0–F1, F2 and F3.

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**Comparators**

Not applicable

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**Outcomes**

The study outcomes are primarily descriptive and based on information documented in routine medical records.

Primary outcomes include how MASH/MASLD is identified and staged, patterns of monitoring, surveillance, care coordination and treatment, and patient demographic, comorbidity and clinical characteristics across fibrosis-stage groups.

Secondary outcomes assess progression across fibrosis stages, particularly progression from compensated to decompensated liver cirrhosis.

Exploratory outcomes include differences in characteristics, management and healthcare use across non-cirrhotic fibrosis stages, and chart-documented diagnosis codes, procedures, medications and healthcare-use patterns that may support future identification of compensated liver cirrhosis in secondary data sources.

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**Data analysis plan**

Analyses will be primarily descriptive and exploratory, conducted overall and by fibrosis-stage group and country. Categorical variables will be summarised using frequencies and percentages, and continuous variables using means, standard deviations, medians, interquartile ranges and ranges.
Disease progression will be assessed using time-to-event methods, including Kaplan–Meier analysis; exploratory Cox proportional hazards models may be used where sample size and data completeness allow.

Internal validity will be supported through predefined cohort/progression definitions, standardised chart abstraction, data-quality checks and sensitivity analyses. Missing data will be described and analyses will generally use available data without formal imputation.

External validity is supported by the multicountry, multisite design; however, findings will primarily reflect patients managed at participating specialist hepatology/gastroenterology sites and may not be fully generalisable to all patients with MASH/MASLD.
Comparative analyses are exploratory and are not intended to establish causal effects.

# Data management

## ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

**Data source(s), other**

MASH-MAP Database: Retrospective medical chart data from participating hepatology and gastroenterology sites in France, Germany, Italy, Spain and the United Kingdom.
Data are abstracted from routine medical records and associated clinical source documents into a study-specific database via an electronic case report form.

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**Data sources (types)**

Electronic healthcare records (EHR)

Laboratory tests and analyses

## Use of a Common Data Model (CDM)

**CDM mapping**

No

# Data quality specifications

**Check conformance**

No

**Check completeness**

No

**Check stability**

No

**Check logical consistency**

No

# Data characterisation

**Data characterisation conducted**

No