

Retrospective Analysis of Mortality in Tafamidis-Treated Japanese Patients with ATTRwt-CM Using the J-COSSA Registry

First published: 21/10/2026

Last updated: 21/10/2026

Study

Planned

Administrative details

EU PAS number

EUPAS1000001025

Study ID

1000001025

DARWIN EU® study

No

Study countries

 Japan

Study status

Planned

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jin Endo

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/05/2026

Study start date

Planned: 02/09/2026

Date of final study report

Planned: 28/02/2027

Study protocol

[B3461129_Protocol_version 1.0_25June2026.pdf_Redacted.pdf](#) (585.79 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Retrospective, observational, longitudinal single-cohort study

Main study objective:

Objectives Stage 1:

- To describe data availability and observed follow-up duration and patterns among patients with ATTRwt-CM treated with tafamidis included in the J-COSSA registry
- To describe patient demographic and baseline characteristics of the study population across predefined analysis sets

Objectives Stage 2:

Primary objective:

- To describe overall survival among patients with ATTRwt-CM following initiation of tafamidis treatment

Secondary objectives:

- To describe overall survival among patients with ATTRwt-CM following initiation of tafamidis treatment stratified with established baseline prognostic factors such as New York Heart Association (NYHA) class and National Amyloidosis Centre (NAC) ATTR stage

Exploratory objectives:

To explore associations between baseline factors and mortality among patients with ATTRwt-CM following initiation of tafamidis treatment

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

VYNDAQEL

Medicinal product name, other

VYNMAC®

Study drug International non-proprietary name (INN) or common name

TAFAMIDIS

Anatomical Therapeutic Chemical (ATC) code

(N07XX08) tafamidis

tafamidis

Additional medical condition(s)

ATTRwt-CM

Population studied

Short description of the study population

Patients with ATTRwt-CM

Study design details

Setting

The study population is derived from the J-COSSA registry, which comprises patients with systemic amyloidosis across Japan, including patients with ATTRwt-CM.

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

J-COSSA registry

Data sources (types)

[Disease registry](#)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No