



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Report for the Summary

A double-blind, randomized, placebo-controlled trial to test the efficacy, safety and tolerability of Dimethyl Fumarate in Friedreich Ataxia (DMF-FA-201).

2022-503016-16-00

Trial Information

Condition(s):

Friedreich's Ataxia

Sponsor:

Dipartimento Di Neuroscienze E Scienze Riproductive Ed Odontostomatologiche Universita Degli Studi Di Napoli Federico II

Trial Phase:

Therapeutic exploratory (Phase II)

Therapeutic area:

Diseases [C] - Nervous System Diseases [C10]

First submitted:

29/12/2022

Last updated:

27/03/2024

FIH:

No

Medical device:

No

Member states concerned:

Italy

Low intervention study:

No

Population type:

Patients

Start of Trial:

10/11/2023

Start of recruitment:

20/11/2023

End of trial:

Global end of trial:

Application Trial Status:

Member State	Application Trial Status	Decision Date
Italy	Authorised	03/05/2023

Overall Trial Status:

Ongoing, recruitment ended