



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Report for the RFI Application

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

Requests for information

Due date:

17/04/2023

Response date:

17/04/2023

Evaluation process:

Assessment Part II

MSC:

Italy

Changes made to the application:

Yes

RFI Unique Identifier:

CT-2022-503016-16-00-IN-006

RFI Status:

Responded

Date submitted:

12/04/2024

Consideration number:

1

Application section parts

Part II - Italy

Application section and document:

Subject information and informed consent form

Consideration:

All references to incidental findings must be eliminated in all information sheets (mature minor, adults, parents and relative privacy consents).

Sponsor response:

all patient documents were corrected.