



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:

19/01/2023

Response date:

18/01/2023

Evaluation process:

Validation

MSC:

Italy

Changes made to the application:

Yes

RFI Unique Identifier:

CT-2022-503016-16-00-IN-001

RFI Status:

Responded

Date submitted:

09/01/2024

Consideration number:

1

Application section parts

Part II - Italy

Application section and document:

Subject information and informed consent form

Consideration:

Please provide three separate documents:

- Information Sheet and Consent Form for adult patients
- Information Sheet and Consent Form for parents or minor legal guardian
- Information Sheet and ASSENT Form for minor patients.

Therefore, please provide three privacy forms.

Sponsor response:

As per your request, we provide three separate documents uploaded in the pertinent CTA section (2022-503016-16-00-IN-001): - Information Sheet and Consent Form for adult patients - Information Sheet and Consent Form for parents or minor legal guardian - Information Sheet and ASSENT Form for minor patients. Moreover, we provided also three separate privacy forms.

Consideration number:

2

Application section parts

Part II - Italy

Application section and document:**Consideration:**

Several documents submitted were indicated as "for publication", but they include signatures. Please indicate documents with signatures as "not for publication" and submit documents without signatures as "for publication".

Sponsor response:

As required, we uploaded in the pertinent CTA sections (2022-503016-16-00-IN-001) the applicable documents as "for publication" and "not for publication".

Consideration number:

3

Application section parts

Part II - Italy

Application section and document:

Recruitment arrangements

Consideration:

Please provide the document "Recruitment and Informed consent procedures" on the AIFA draft.

Sponsor response:

As required, the "Recruitment and Informed consent procedures" was uploaded in the specific CTA section (2022-503016-16-00-IN-001).

Consideration number:

4

Application section parts

Part I - Regulatory

Application section and document:

Protocol

Consideration:

In Ctis is not required an EudraCT Number. We would like to ask for clarification on the reasons why you have submitted the document "DMF-FA-201_Application for EudraCT Number".

Sponsor response:

This document was uploaded because the EudraCT Number is mandatory, as also confirmed in the CTIS newsflash – 13 January 2023 " Sponsors will be prevented from submitting an initial application that does not contain a valid EudraCT number".