



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:

12/04/2023

Response date:

07/04/2023

Evaluation process:

Assessment Part II

MSC:

Italy

Changes made to the application:

Yes

RFI Unique Identifier:

CT-2022-503016-16-00-IN-004

RFI Status:

Responded

Date submitted:

03/04/2024

Consideration number:

1

Application section parts

Part II - Italy

Application section and document:

Subject information and informed consent form

Consideration:

Consideration number RFI-CT-2022-503016-16-00-IN-002-02

Consideration: Since the CRF was not available, it was not possible to complete this section: the CRF must be provided.

Sponsor response: the CRF was not provided as no specific section for CRF is foreseen in the CTIS. We uploaded the screen shot of last available draft, as the CRF will be finalized once the protocol will be approved, in the protocol documents section.

Consideration of CE: For privacy reasons in the CRF the date of birth can not be complete (for example remove the day)

Sponsor response:

Thank you for raising this point, in the final version of CRF, that will be finalized once the protocol will be approved, the complete date of birth will be removed, only the age will be collected.

Consideration number:

2

Application section parts

Part II - Italy

Application section and document:

Subject information and informed consent form

Consideration:

Consideration number RFI-CT-2022-503016-16-00-IN-002-01

INFORMED CONSENT FORM – GENITORE Version 1.1 Jan 11, 2023 ASSENSO INFORMATO FINALIZZATO ALL'INSERIMENTO IN UNA SPERIMENTAZIONE CLINICA DESTINATO AD UN MINORE DI ETA' COMPRESA TRA 12 e 17 ANNI

Consideration: 2. There are references also to „genetic incidental findings“, but in the Protocol the analyses that will be performed are not completely described (mtDNA, nDNA, pathway of Nrf2). So, it is not possible to define if these analyses could have incidental findings

Sponsor response: There will be no genetic incidental findings as this is an expression study and the output cannot reveal “incidental findings”. We amended the IC accordingly

Consideration of CE: There are still phrases to remove in the “informative” “Dall'esecuzione delle analisi previste dalla sperimentazione potrebbero emergere risultati inattesi (ad es. relativi alla possibilità di sviluppare in futuro altre malattie). Queste informazioni le verranno fornite solo su tua indicazione e dei tuoi genitori. Avrai inoltre la possibilità di scegliere di ricevere solo le informazioni eventualmente utili per la cura della salute tua e/o dei tuoi familiari potenzialmente affetti e/o per consentirti di adottare una scelta riproduttiva consapevole”. In the “consenso/assenso per minori” (notizie inattese) the phrase “incluse quelle genetiche” has to be removed.

Sponsor response:

The sentence has been removed.

Consideration number:

3

Application section parts

Part II - Italy

Application section and document:

Subject information and informed consent form

Consideration:

Consideration number RFI-CT-2022-503016-16-00-IN-002-07

Consideration: Remove the phrases "Una volta scaduto il termine di conservazione sopra indicato, i dati verranno cancellati ovvero resi anonimi in modo che non sia più possibile risalire, in modo diretto o indiretto, all'identità dell' Interessato;

Sponsor response: This sentence was erroneously inserted in the section referring to the site, It has been moved in the section relevant to Sponsor

Consideration of CE: In the document "Privacy adulti/genitori/minore": Change the phrase "Una volta scaduto il termine di conservazione sopra indicato, i dati verranno cancellati"

DELETE: "ovvero resi anonimi in modo che non sia più possibile risalire, in modo diretto o indiretto, all'identità dell' Interessato"

Sponsor response:

The sentence has been removed from privacy consent adulti, genitori and minore.

Consideration number:

4

Application section parts

Part II - Italy

Application section and document:

Subject information and informed consent form

Consideration:

Consideration number RFI-CT-2022-503016-16-00-IN-002-01

INFORMED CONSENT FORM – GENITORE Version 1.1 Jan 11, 2023 ASSENSO INFORMATO FINALIZZATO ALL'INSERIMENTO IN UNA SPERIMENTAZIONE CLINICA DESTINATO AD UN MINORE DI ETA' COMPRESA TRA 12 e 17 ANNI

Consideration: 15. Add that in case of withdrawal biological samples will be destroyed

Sponsor response: we added this option in section “ il consenso è definitivo?”

Consideration of CE: In all the informative the new phrase has to be changed in “Nel caso di ritiro del consenso, nessuna altra procedura di studio verrà eseguita, incluso il prelievo di campioni biologici, e quelli raccolti verranno subito distrutti”

DELETE: "dopo le analisi previste dal protocollo”

Sponsor response:

Thank you for your comment, we amended the sentence in all the informative.