



Fullcro S.r.l.
Via Ignazio Guidi, 3 - 00147 Roma
Tel. +39 06.58300326 / 327
P. Iva e Cod. Fisc: 12073321007
Cap. Soc. € 50.000 i.v.
www.fullcro.org

To
**Ufficio Sperimentazione Clinica
AIFA
Via del Tritone, 181
00187 Roma**

Roma, 18/01/2023

Object: EU CT number 2022-503016-16-00, Responses to RFI considerations of 9 January 2023

EudraCT number	2021-006274-23
EU CT number	2022-503016-16-00
Protocol Title	A double-blind, randomized, placebo-controlled trial to test the efficacy, safety and tolerability of Dimethyl Fumarate in Friedreich Ataxia.
Protocol Code	DMF-FA-201
Phase	II
Sponsor	Dipartimento di Neuroscienze, Scienze Riproduttive e Odontostomatologiche Università degli Studi di Napoli Federico II Via Sergio Pansini, 5 - 80131 Napoli, Italia
Applicant	Fullcro srl, Via Ignazio Guidi 5. 00147 Roma, Italia
Coordinator Site	UOS Centro Sclerosi Multipla AOU "Federico II" Via Pansini, 5 80131 Napoli

Fullcro srl, as representative of the Sponsor, replies to the RFI considerations in object with the following responses. As consequence, the application was changed only in the relevant documents sections of Form, Part I and Part II.

Consideration number RFI-CT-2022-503016-16-00-IN-001-01 - Application section parts Part II - Italy

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 RFI-CT-2022-503016-16-00-IN-001-02 - Application section parts Part II – Italy

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 Please indicate documents with signatures as "not for publication" and submit documents without signatures as "for publication".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we uploaded in the pertinent CTA sections (2022-503016-16-00-IN-001) the applicable documents as "for publication" and "not for publication".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 RFI-CT-2022-503016-16-00-IN-001-03 - Application section parts Part II - Italy

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 RFI-CT-2022-503016-16-00-IN-001-04 - Application section parts Part I - Regulatory

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".

FULLCRO S.r.l.
Moira Cordisco
Start-up Manager

For every necessity, please contact:
Moira Cordisco
FULLCRO s.r.l.
Via Ignazio Guidi, 3 - 00147 Roma
Tel +39 06 58300326/327
Fax +39 06 58300309
moira.cordisco@fullcro.org