

“DECLARATION OF INTERESTS” DOCUMENT

(REGULATION 536/2014, ADDENDUM I, LETTER M, No. 66 E ART. 6 PARAGRAPH 4, LEGISLATIVE DECREE No. 52 OF 14 MAY 2019, AS MODIFIED ART. 11-BIS, PARAGRAPH 1, LEGISLATIVE DECREE 19 MAY 2020, No. 34, CONVERTED INTO LAW No. 77 OF 17 JULY 2020)

All member states, for each clinical trial, must evaluate the aspects pertaining to part II of the Regulation, which includes the “**Declaration of interests**”, which must be completed by the investigators ¹ and is part of the application file.

This form has been created and approved by the Coordinating Site based on the form drafted by the EU Clinical Trials Expert Group in accordance with Regulation (EU) no. 536/2014 on clinical trials on medicinal products for human use. However, this form is also relevant pursuant to Directive 2001/20/CE.

The following declaration refers to the clinical trial indicated below

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

To be conducted at the Site

UOS Centro Sclerosi Multipla
AOU “Federico II”
Via Pansini, 5
80131 Napoli
Italy
Coordinating Site [YES] {NO}

I, the undersigned, Dr Francesco Saccà

engaged at the facility

Dipartimento di Neuroscienze, Scienze Riproduttive ed Odontostomatologiche
Università Federico II, Napoli
Via Pansini, 5
80131 Napoli

Principal Investigator [YES] {NO}

in the aforementioned trial,

¹) Pursuant to Regulation (EU) no. 536/2014, ART. 2 paragraph 2 no. 15 and 16, the definition of “investigator” is: an individual responsible for the conduct of a clinical trial at a clinical trial site; “Principal Investigator”: an investigator who is the responsible leader of a team of investigators who conduct a clinical trial at a specific site.

I HEREBY STATE

That the information in the tables below are **all** the interests, activities and/or relationships I have with the trial Sponsor(s) and in general with the pharmaceutical industry:

Table 1.A Relevant activities⁽²⁾

Role/position held at a company in relation to a particular product/group of products	NO	Ongoing or in the past year	Over 1 year ago, but less than 3 years ago	Over 3 years ago ²
A) Employee (worker – middle manager – executive)	X			
B) Scientific Consultant (³)		X	X	X
C) Member of a scientific collegiate board with advisory functions for the trial sponsor		X	X	X
D) Principal Investigator		X	X	X
E) Investigator		X	X	X

Table 1.B – identification of potential areas of conflict

Type of activity (Table 1.A)	Name of the company (<u>SPONSOR AND NOT</u>) for you have performed a relevant activity	Products similar to the investigational product	
A) employed work B) Individual scientific consultancy C) member of collegiate bodies (e.g. Advisory Board,	NO Lexeo Therapeutics, Novartis, argenx, Avexis Alexion, Almirall, argenx, Avexis, Biogen, Lexeo Threapeutics, Novartis	Dimethylfumarate (Almirall, Biogen)	

²) If you select a box in any column other than the “NO” column, information regarding the products concerned must be provided in Table 1.B. If you declare an interest in table 1.A, but fail to provide the relevant information in Table 1.B, the study may not be submitted to the Ethics Committee.

³) For the purposes of this document, any professional expert who provides services to the Sponsor in a particular field, whether remunerated or not (personally and/or institutionally), falls within this definition.

Steering Committee/ Academy, ...)		
D) training activity (e.g. ECM, preceptorship)	Alexion, argenx, Biogen, Novartis	
E) PI or Investigator	Alexion, argenx, Immunovant,	
F) Other	Novartis, Prilenia, Sanofi	

(→ Use additional sheets if necessary)

2 - DECLARATION OF FINANCIAL, FAMILIAL INTERESTS OR INTERESTS OF ANOTHER NATURE

Table 2.A – Equity shares, funds/loans

	NO	YES direct	YES Indirect ⁽⁴⁾	Company name	Indicate the share as a % or nature/amount of funds
I am a shareholder in a pharmaceutical company	X				
My Department receives funds or other funding from a pharmaceutical company (and I do not receive any remuneration)	X				
I am a beneficiary of funds or other funding from pharmaceutical companies	X				

Table 2.B – Family relationships, patents

	NO	YES	Name of company and products	Description
I have a marriage to, I cohabit with or I am a first or second degree relative of a person linked to pharmaceutical companies by subordinate employment relationships or professional positions	X			
I have a patent on the investigational medicinal product or a related product	X			

⁴⁾ For the purposes of this document, if the shareholder is a spouse, by a cohabitant or children, parents or siblings is considered to be indirect. If you select any box in the "YES, indirect" column, information in relation to the company, period of activity and products involved must be provided in the subsequent columns. If you fail to provide the relevant information, the study may not be submitted to the Ethics Committee.

(→ Use additional sheets if necessary)

If you believe that there is any other interest or fact to report, please specify below :

.....

(→ Use additional sheets if necessary)

*** **

I declare that I have no other interests, activities and/or direct or indirect relationships in or with the pharmaceutical industry, economic interests, institutional affiliations or personal interests that could affect my impartiality.

I also Declare, to the best of my knowledge and under my responsibility, that the information provided above is true and accurate.

I undertake to update this promptly, including after the start of the trial.

Signature: []

Firmato digitalmente da

Date: December 10th 2022
