Regulation (EU) no. 536/2014 - Part II Documents Form Approved by the Coordinating Site version of L3/01/2022 no. 1

DOCUMENT "CURRICULUM VITAE OF CLINICAL RESEARCH COORDINATOR AND DATA MANAGER"

(REGULATION EU no. 536/2014, ART.49, ANNEX I, SECTION M, PARAGRAPH 65)

All member states, for each clinical trial, must evaluate the aspects pertaining part II of the Regulation, which include, among others the "Curriculum Vitae of the Investigator", which must be provided by the investigator, according to the form indicated below, for the applicable parts, and is part of the application file.1 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. 536/201,4 on clinical trials on medicinal products for human use. However, this form is also relevant pursuant to Directive 2OOL/20/CE.

Personal Information

Name: Giulia Ferrazzi

Title: Master's Degree in Pharmacy

Profession: Clinical Study Coordinator and Data Manager

Current position: Research fellowship

<u>Professional Registration</u>i

Registration number: 16138

Registration body: Ordine dei Farmacisti di Roma

Registration expiry date (if applicable):

Registration state/province (if applicable): Italy, Rome

Education and Qualificationsii

Institution name Qualification Year

Tor Vergata University of Rome Master's Degree in Pharmacy 2018

Regulation (EU) no. 536/2014 - Part II Documents Form Approved by the Coordinating Site version of L3/01/2022 no. 1

DOCUMENT "CURRICULUM VITAE OF CLINICAL RESEARCH COORDINATOR AND DATA MANAGER"

(REGULATION EU no. 536/2014, ART.49, ANNEX I, SECTION M, PARAGRAPH 65)

Current employment

Institution name: "Sapienza" University of Rome

Department: Hematology Dept/ Translational and Precision Medicine Dep.

Institution address: Via Benevento, 6

Telephone number:

E-mail address:

<u>Professional experienceⁱⁱⁱ</u>							
Position	Institution name and department	Start year	End year				
Pharmacist	Click or tap here to enter text.	02/2019	05/2022				
Post-graduate Internship	Tor Vergata University of Rome, Material Science Dep	09/2018	02/2019				

Relevant clinical trial/study experience ^{iv} Year						
Role	Therapeutic area	Type of trial	started	Phase	Ongoing	
Study Coordinator	Haematology Diseases	Interventional Trial	2022	II, III	Yes	
Study Coordinator	Rare Diseases	Observational Trial	2022		Yes	

Regulation (EU) no. 536/2014 - Part II Documents Form Approved by the Coordinating Site version of L3/01/2022 no. 1

DOCUMENT "CURRICULUM VITAE OF CLINICAL RESEARCH COORDINATOR AND DATA MANAGER"

(REGULATION EU no. 536/2014, ART.49, ANNEX I, SECTION M, PARAGRAPH 65)

Training						
Research training (including GCP)	Institution name	Year obtained				
Certificate GCP ICH E6	Transcelerate	2024				
IATA	Formazione Nel Farmaceutico.com	2023				

Date completed: 23/04/2024

Signature (if required):

ⁱ As per national legislation

ii Relevant to be an investigator

iii This should cover the preceding 10 years as a maximum

^{iv} Idem

^v As per national legislation, a signed version of the CV should be included in the trial master file however, a signed version may not be required for regulatory review, this should be confirmed nationally.