

"CURRICULUM VITAE PRINCIPAL INVESTIGATOR"

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

Each Member State, for each clinical trial, will have to evaluate the aspects related to Part II of the Regulation among which there is the "**Curriculum vitae of the principal investigator**". This document must be prepared by the investigator, according to the model shown below, for the applicable parts, and is part of the application dossier.¹

This model has been developed and approved by the National Coordination Centre of Ethics Committees, based on the model elaborated by the EU Clinical Trials Expert Group in compliance with Regulation (EU) no. 536/2014 on clinical trials on medical products for human use. However, this model is also relevant under Directive 2001/20/EC.

Personal Information

Name: Elisa Tinazzi
Title: Medical Doctor
Profession: Medical Doctor- Specialist in Internal Medicine
Current position: Medical Assistant at General Medicine B, AOUI Verona

Professional Registrationⁱ

Registration number VR06717
Registration body: Ordine Medici Chirurghi di Verona
Membership expiry date (if applicable): Click or tap here to enter the text.
Registration state/province (if applicable): Click or tap here to enter the text.

Education and qualificationsⁱⁱ

⁽¹⁾ Pursuant to the EU REGULATION n. 536/2014, ART. 2 par. 2 n° 15 and 16 an "investigator" is defined as: a person responsible for conducting a clinical trial at a clinical trial site; 'principal investigator' means an investigator who leads, as head, a team of investigators to conduct a clinical trial at a given site.

Institution name	Qualification	Year
University of Verona	Degree In Medicine and surgery	1997
University of Verona	Specialization in Internal Medicine	2002
University of Verona	Phd In Clinical Proteomics	2008

Current employment

Institution name:	Azienda Ospedaliera Universitaria Integrata di Verona
Department:	General Medicine B
Institution address:	Ospedale Borgo Roma- P.le L.A. Scuro, 10, 37134 Verona, Italy
Phone number:	+39 045 8124759
E-mail address:	elisa.tinazzi@univr.it

Professional experience ⁱⁱⁱ

Position:	Name of institution and department:	Start year	End year
University researcher ad medical assistant	Department of Medicine, University of Verona and University Hospital of Verona	2002	2012
Assistant Professor	Department of Medicine, University of Verona and University Hospital of Verona	2012	2019
Medical Assistant	Department General Medicine B, University Hospital of Verona	2020	--

Relevant experience in clinical trials/clinical studies ^{iv}

Role	Therapeutic area	Type of research	Phase
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			Start year		In progress
Sub Investigator	Rheumatology	Interventional Trial	2008	Other	No
Principal Investigator	Rheumatology	Clinical Study	2006	Other	No
Principal Investigator	Immunology and Rheumatology	Clinical Study	2018	Other	No

<u>Training</u>		
Research training (including GCP)	Institution name	Year of achievement
NIS Good Practices	Janssen	2022
NIS Investigator Safety Training	Janssen	2022
ICH GOOD CLINICAL PRACTICE E6 (R2)	The Global Health Network	2023

Date completed:
March 2th 2023



ⁱ As required by national legislation

ⁱⁱ Relevant to being an investigator

ⁱⁱⁱ This should cover the preceding 10 years as a maximum

^{iv} *Idem*