

Investigator Curriculum Vitae

This template may be used by Sponsors of clinical trials as part of the application dossier.

A separate document should be completed and submitted for each site.

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<u>Personal Information</u>	
Name	Maddalena Sansovini
Title	MD
Profession	Nuclear Medicine physician
Current position	Nuclear Medicine Unit, IRCCS Istituto Romagnolo per lo Studio dei Tumori (IRST), "Dino Amadori", Meldola, Italy

Since 20/07/2021 I take part of the Phase 1 Clinical Trials Unit in IRCCS IRST

<u>Professional Registration¹</u>	
Registration number	4313
Registration body	Italian Medical Association
Registration expiry date (if applicable)	N.A.
Registration state/province (if applicable)	Forlì-Cesena (FC) - Italy

<u>Education and Qualifications²</u>		
Institution name	Qualification	Year
University of Bologna	Medical and surgical degree	2022
University of Bologna	Specialization in Medicine and Surgery	2007

<u>Current employment</u>	
Institution name:	IRCCS Istituto Romagnolo per lo Studio dei Tumori (IRST), "Dino Amadori"
Department:	ADVANCED PROCEDURES AND TECHNOLOGIES
Institution address:	VIA MARONCELLI, 40 MELDOLA (FC), Italy
Telephone number:	+39 0543 739100
E-mail address:	maddalena.sansovini@irst.emr.it

<u>Professional experience³</u>
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¹ As per national legislation

² Relevant to be an investigator

³ This should cover the preceding 10 years as a maximum

Investigator Curriculum Vitae

Position	Institution name and department	Start year	End year
Nuclear Medicine physician	IRCCS Istituto Romagnolo per lo Studio dei Tumori, "Dino Amadori" - IRST S.r.l.	2008	2023
In charge person of "Struttura Semplice"	IRCCS Istituto Romagnolo per lo Studio dei Tumori, "Dino Amadori" - IRST S.r.l.	2024	today

Relevant clinical trial/study experience⁴					
Investigator role	Therapeutic area	Type of trial	Year started	Phase	Ongoing
Principal Investigator	LUBASKET "Radiometabolic Therapy (RMT) with 177Lu PSMA in PSMA PET/CT positive advanced/metastatic tumours: a basket trial"	Interventional Trial	2023	Phase II	No
Principal Investigator	LUFOR "Receptor radionuclide therapy with 177Lu-DOTATOC (177Lu-edotreotide or 177Lu-octreotide) in SSTR positive patients: a multicenter, prospective, phase II trial"	Interventional Trial	2023	Phase II	Yes
Principal Investigator	LuMIERE: Studio di fase I/II multicentrico in aperto, non randomizzato volto a esaminare la sicurezza, la tollerabilità, la farmacocinetica, la dosimetria e l'attività preliminare di [177Lu]Lu-FAP-2286 in partecipanti con tumore solido avanzato	Interventional Trial	2023	Phase I-II	No
Principal Investigator	Efficacy, safety and patient-reported outcomes of peptide receptor radionuclide therapy with 177Lu-edotreotide compared to everolimus in somatostatin receptor positive neuroendocrine tumors of the lung and thymus. The LEVEL Trial	Interventional Trial	2022	Phase III	Yes

⁴ Idem

Investigator Curriculum Vitae

Training		
Research training (including GCP)	Institution name	Year obtained
Trial Clinici: cosa insegnano gli audit?	IRCCS IRST	2014
Scientific Writing	IRCCS IRST	2014
Progettazione Europea Horizon 2020: Opportunità e Scenari Applicativi	IRCCS IRST	2014
La radioprotezione in IRST 2015	IRCCS IRST	2015
BLS-D-basic Life Support-Defibrillation	IRCCS IRST	2015
HeartStart MRX monitor/defibrillatore	IRCCS IRST	2016
Prevenzione delle condotte suicidarie in IRST	IRCCS IRST	2016
Trial fase 1: i requisiti fondamentali	IRCCS IRST	2016
Data Protection. Gli strumenti messi a disposizione da IRST	IRCCS IRST	2018
La radioprotezione in IRST 2015	IRCCS IRST	2018
Advanced Life Support	Italian Resuscitation Council	2021
Good Clinical Practice Principi Base 2021	Az. AUSL Romagna	2021
Basic Life Support Defibrillation per sanitari	Italian Resuscitation Council	2021
Il Sistema Qualità in Unità Clinica di Fase I	IRCCS IRST	2021
Simulazione di emergenza UCF1	IRCCS IRST	2022
Refresh sulle procedure relative al percorso del paziente di Fase I	IRCCS IRST	2022
Il nuovo Regolamento europeo sulla sperimentazione clinica e l'applicazione delle GCP	IRCCS IRST	2022

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Training		
Research training (including GCP)	Institution name	Year obtained
UCF1: il sistema qualità 2022-23 - Mod.1-2	IRCCS IRST	2022
Simulazione di emergenza UCF1	IRCCS IRST	2023
Good Clinical Practice: dalla teoria alla pratica	IRCCS IRST	2023
Basic Life Support Defibrillation per sanitari	Italian Resuscitation Council	2023
FORMAZIONE COORDINATORI DEI GRUPPI MULTIDISCIPLINARE	Az. AUSL Romagna	2024
SIMULAZIONE EMERGENZE UCF1	IRCCS IRST	2024
GCP: applicazione in studi profit e no-profit 1	IRCCS IRST	2024
IV CONVEGNO ITALIANO SULLE TERAPIE AVANZATE E RADIOFARMACI"	IRCCS IRST	2024
La radioprotezione del lavoratore nelle attività sanitarie. Percorso regionale Medicina Nucleare	Regione Emilia Romagna	2024
Advanced Life Support	Italian Resuscitation Council	2021
SIMULAZIONE EMERGENZE UCF1	IRCCS IRST	2025
Le nuove Linee Guida di Buona Pratica Clinica ICH GCP E6 (R3): analisi dei cambiamenti qualitativi e dell'impatto nella pratica degli studi clinici	IRCCS IRST	2025

Last Advanced Life Support (ALS) certificate (date)	20-21/03/2025
Last Basic Life support and Defibrillator (BLS/D) certificate (date)	14/12/2023
Last Clinical Emergency Simulation Course certificate (date)	27/03/2026
Last Good Clinical Practice E6R3 (GCP) training certificate (date)	27/06/2025

I authorize the use of my personal data in accordance with Legislative Decree 196/2003 and European Regulation 679/2016 - GDPR - on the processing of personal data.

Date completed:	14.4.2026
Signature	