FONDAZIONE IRCCS ISTITUTO NAZIONALE DEI TUMORI	**CURRICULUM VITAE**

Personal Information

Sara Pessina

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Current Position

"Phase I Program" Coordinator – Senior Study Coordinator

Education

Nov 2016 - Feb 2017: Approval and registration in the biologist professional register.

Nov 2012 - Nov 2015: PhD in Translational and Molecular Medicine, University of Milano-Bicocca.

Feb 2011 - Oct 2012: Master's degree in Biology Applied to Research in Biomedicine, University of Milan.

Oct 2007 - Dec 2010: Bachelor's degree in Biology, University of Milan.

Previous Professional Experience

May 2018 - Dec 2018: Data Entry, Clinical Trial Center, Fondazione IRCCS Istituto Nazionale dei Tumori, Milan.

Dec 2015 - Dec 2017: Post-doctoral researcher, Brain Tumor Immunotherapy Lab, Unit of Molecular Neuro-Oncology, Istituto Neurologico C. Besta, Milan.

Nov 2012 - Nov 2015: PhD student, Unit of Molecular Neuro-Oncology, Istituto Neurologico C. Besta, Milan.

Experience in Clinical Research

Phase I Program coordination and management of > 70 phase I/II clinical trials:

- Knowledge and application of Good Clinical Practice (GCP)
- Knowledge and drafting of Standard Operating Procedures (SOP)
- Knowledge of current legislation about Clinical Research
- Coordination and management of the team/structures/consultants involved in Phase I Program
- Coordination of the team involved in the studies
- Management of contacts with the Sponsor, CRO, Pharmacovigilance, Auditors/Inspectors
- Supervision and support during internal and external audits and inspections by Competent Authorities
- Supervision and tutoring of junior study coordinators
- Feasibility analysis of new studies/projects
- Data entry activities: compilation of eCRFs and resolution of queries. Use of the main eCRF systems: RDC, Rave EDC, InForm, Veeva, REDCap, OpenClinica.
- Consultation of reporting systems for the collection of Source Data

- Management of IWRS systems
- Management of study documentation according to GCP and Investigator Site File (ISF)
- Planning and management of monitoring visits: from pre-study to close out visit

Trainings in Clinical Research:

11 Jan 2024 – 18 Mar 2024: training course for Quality Assurance and Auditor (SIMeF)

23 Jan 2024: ICH-GCP training with integrated Addendum E6 (R2): ICH E6 GCP investigator site personnel training.

09 – 10 May 2023: Project Management in Clinical Research (IQVIA)

Annually: "Phase I clinical trial" training course (Istituto Nazionale dei Tumori).

Annually: "Clinical Trial Management" training course (Istituto Nazionale dei Tumori).

Jan - Feb 2018: Clinical Research Training Course "Missione CRA" (CRAsecrets.com, Yghea CRO): 48-hour training course in clinical research in compliance with the D.M. 15.11.2011.

Milan, 02 APR 2024

Sara Pessina

In compliance with the Italian legislative decree no. 2003/196 and art. 13 of the EU regulation 2016/679, I hereby authorize you to use and process my personal data.