

JOB DESCRIPTION

Position title: Clinical Trial Assistant	
Line Manager	Coordination Center of INCiPiT (key reference roles: Senior Scientific Managers)
Principal Accountabilities	<p>To provide support to the general activities handled by the INCiPiT Coordinating Center Team, in terms of:</p> <ul style="list-style-type: none"> ▪ Financial tracking (invoicing, finalization of Work Orders, ad hoc contracts, tracking of the administrative activities of the NHs involved in the c4c project/studies) ▪ Tracking of the agendas of pre-defined meetings/commitments and organization of ad hoc meetings, as per specific Team involvement ▪ Distribution of materials to Operative Teams, Study Teams and or Scientific Teams ▪ Support the activities of INCiPiT Working Groups, as requested ▪ Support the interactions with local INCiPiT referees, also to retrieve specific information. ▪ Bridging with CROs and/or Sponsors to support specific activities, such as: study scientific/operational feasibilities, identification of local costs and finalization of study budgets, identification of the local correct stakeholder for contract negotiations. ▪ Support the internal CRAs and/or the Clinical Project Manager (CPM) in performing the regulatory mapping for a clinical study/clinical project ▪ Supervise the flow of regulatory documentation from the NHs to the allocated vendor for TMF/ISF management (therefore to supervise the specific activity when allocated on the internal regulatory resource) ▪ Perform directly any regulatory submission (when requested by the Sponsor) and maintain contacts with Regulatory Authorities and/or Ethics Committees.
Professional Background and Experience	<ul style="list-style-type: none"> ▪ Scientific Degree in Science ▪ Research or health care related academic or work experience ▪ From 2 to 3 years of experience in Clinical Trials coordination and or Clinical Development activities and a minimum of one (1) year of administrative experience (or equivalent training)
Technical Competencies	<ul style="list-style-type: none"> ▪ Knowledge of GCPs and of Regulatory/ethics obligations, laws and regulations for clinical trials/clinical development management ▪ Very good Knowledge of the main Office software (Word, Excel, Power Point, etc.) ▪ Capability to get quick familiarity with CTMSes and databases, research dedicated ▪ Good knowledge of quality systems and quality assurance assets
General Competencies	<ul style="list-style-type: none"> ▪ Professional Knowledge of English, both spoken and written ▪ Very good organizational skills, ability to manage multiple tasks and meticulous attention to detail ▪ Very good time management skills ▪ Very good written and verbal communication skills ▪ Advanced ability and attitude on team working and in particular good capability to work in a matrix environment
Salary	<ul style="list-style-type: none"> ▪ To be discussed during the interview. Benchmarking with the present position as defined in academic organizations is proposed.