

JOB DESCRIPTION

	Position title: Clinical Project Manager (CPM)
Line Manager	Coordination Center of INCIPIT (key reference roles: Senior Scientific Managers)
Context	INCiPiT (Italian Network for Paediatric Clinical Trials) is a no profit Consortium composed by the main Italian children's hospitals, the largest departments of paediatrics as well as national and international paediatric therapeutic networks coordinated by Italian institutions. The scope of INCiPiT is to foster high-quality research on drugs in children in Italy; INCiPiT aims to support the planning, conduction and completion of all types of clinical studies in the paediatric population, by providing expertise and coordinating logistical support to academic investigators, as well as to pharmaceutical industries and contract research organisations.
Job Responsibilities	<p>The CPM assures the implementation of Projects Plans, as assigned.</p> <p>The CPM is responsible for the oversight of the planning and execution of assigned clinical studies. In close collaboration with the Project Leader, the position is accountable for the management of complex, either mono- or multi-center clinical research projects in different paediatric disease areas. The Clinical Project Manager ensures all studies are executed on time, in line with the allocated budget and conducted in compliance with GCPs (and/or GPPs) and all applicable Guidelines & Regulations. The CPM is the primary Sponsor point of contact on all project contents, he/she leads a cross-functional study team and he/she is accountable for the management of the GCP monitoring personnel assigned to each study endorsed by the Sponsor.</p>
Skills and qualifications required	<ul style="list-style-type: none"> • Bachelor's degree in Life Sciences, Health Care field or an equivalent combination of education, training & experience; PhD/Masters of Science degree preferred. • Previous experience in clinical studies and research studies management of at least 3 years; CRO/Pharma experience preferred • Preferable experience in the management of EU funded projects • Proficient computer skills, in relation to standard systems and softwares and able to easily shift to new IT systems, as requested by specific activities (i.e. CTMS, databases, etc...) • Excellent proficient in English: mandatory the capability to write even complex texts (with or without scientific contents), and to have high level professional spoken interactions with any kind of foreign stakeholder
Technical Competencies	<ul style="list-style-type: none"> • Knowledge of, and skill in applying, the GCPs (for both pharmaceutical compounds and medical devices) and GPPs • Knowledge of GMP standards, with reference to the management of Investigational Medicinal Product and any applicable related process • Knowledge of GLP standards • Knowledge of regulatory/ethical national and international requirements, in terms of clinical trials approvals, conduction and management

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	<ul style="list-style-type: none"> • Knowledge of Pharmacovigilance requirements, according to the applicable and actual laws and regulations • Knowledge of quality systems and quality assurance assets
Salary	To be discussed during the interview. Benchmarking with a senior position as defined in academic organizations is proposed.