JOB DESCRIPTION

	Position title: Clinical Research Associate (CRA)
Line Manager	Coordination Center of INCIPIT (key reference roles: Trial Operational Coordinator and Senior Scientific Manager)
Purpose of the Job	Assures the implementation of Projects Plans, as assigned. Assumes site administration and site monitoring responsibilities for clinical studies in compliance with the clinical protocol and according to INCIPIT and/or Sponsor Standard Operating Procedures (SOPs), ICH Guidelines, Good Clinical Practices (GCPs), and applicable regulatory requirements. Supports the Clinical Study Manager (and/or the Sr. CRA) in the study management activities, contributing to the finalization/implementation of study specific Plans and Procedures, or both national and global studies. Supports the Clinical Study Manager in performing the pre-Feasibility and Feasibility activities assigned to the INCIPIT Coordinating Center and conducted within the Consortium. Is assigned with special tasks, within some of the activities of the Consortium, such as (but not limited to): • Organization of the periodic INCIPIT Board of Directors and General Assembly • Reinforcement of INCIPIT infrastructure (dedicated working groups, GDPR organization, etc) • INCIPIT Special Project • Application to national and international Research Funding Programs • Clinical Development Programs, managed in joint venture/collaboration/commission of commercial entities • Collaboration with other national/international Research and Clinical Research Networks/Consortia/Foundations • Interactions with other National Hubs within the frame of the c4c (conect4children) Network
Principal Accountabilities	▪ To perform the selection (pre-feasibility and Feasibility processes) and qualification processes of clinical sites in compliance with the Clinical Project requirements, the Sponsor, involved external CROs (if any), appointed Networks ▪ To collaborate with the Clinical Study Manager (CSM) in drafting the study-related documentation such as (but not limited to) the Monitoring Plan (MP), the Deviation/Violation Management Plan, the Risk Mitigation and Management Plan, the Communication Plan, the study-specific procedures/Working Instructions, the CRF Completion Guideline, according to the instructions provided by the Sponsor ▪ To support the CSM in interacting with the PhV Responsible (Officer) allocated by the Sponsor to the clinical project/study, with particular focus on the finalization of the study-specific Safety and Pharmacovigilance Plan ▪ To support the INCIPIT Coordination Center Team in coordinating the bridging activities with the c4c NH Pv RP and the NH Lead Pharmacist/s

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	▪ To implement and maintain contacts with the personnel of the selected clinical sites and act as the first contact point (Point of Contact-PoC) both for the clinical site and the Responsible of the study ▪ To support the CSM and the Clinical Trial Assistant (CTA) with the implementation of the activities pertaining the regulatory start-up of the clinical Project/study ▪ To support the CSM in managing INCIPIT's Vendors ▪ To support the CTA in organizing and maintain the TMF and the site specific files (ISFs), according to the applicable SOPs ▪ To participate in the organization and implementation of Kick-off Meetings and Investigator's Meetings and drafting of specific material according to the Study Responsible/Study Team request ▪ To identify specific administrative/financial/organizational requirements of the clinical sites needed for the sites' activation ▪ To organize and conduct the Site Qualification Visits (SQVs), Site Initiation Visits (SIVs), the periodic site monitoring visits (SMVs) and the close-out visits (COVs), all of them both on site and/or in remote, as required by the study specific MP ▪ To prepare accurate monitoring visits reports, in compliance with contents and timing defined in the MP ▪ In case an eCRF is available (as well as other electronic devices used within the trial) to implement remote monitoring activities with identification of recurrent issues, in order to provide immediate resolution and to support the clinical sites for the proper performance of data entry and maintenance of accurate data cleaning activities ▪ To support the CSM to prepare and maintain study updates (either through managing platforms or tools developed ad hoc) and to monitor the related costs progression (study budget management) ▪ To conduct compliance/co-monitoring visits, according to Sponsor's compliance programs, in order to verify the compliance of the performed activities with the study objectives and the expected quality standards ▪ To support the CSM and the CTA with the completion of additional regulatory/approval activities in case of amendments to the clinical program/study or to specific documental parts of the study itself ▪ To participate (and support the planning and organization, if required) to meetings and teleconferences with Sponsors/study Teams/Vendors, in order to maintain the continue control of the performed activities and the achievement of milestones defined during the scheduling of the study activities ▪ To support the training activities of the sites' staff, as well as of the INCIPIT new employees and/or of the INCIPIT local personnel, as needed ▪ To perform the periodic reporting activity to the CSM and /or Study Responsible/Study Team
Professional Background and Experience	▪ Scientific Degree ▪ Successfully completion of a CRA Trainee Program, according to the requirements of the Italian Ministry Decree 15 Nov 2011 (CRA National Certification Program) ▪ From 3 to 5 years of experience in Clinical Monitoring
Technical Competencies	▪ Good knowledge of, and skill in applying, the GCPs (for both pharmaceutical compounds and medical devices) ▪ Knowledge of GMP standards, with reference to the management of Investigational Medicinal Product ▪ General knowledge of GLP standards ▪ Good knowledge of regulatory/ethical national and international requirements, in terms of clinical trials conduction and management ▪ Knowledge of Pharmacovigilance requirements, according to the applicable and actual laws and regulations ▪ Basic knowledge of quality systems and quality assurance ▪ Knowledge of computerized systems specifically applicable to this area

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General Competencies	▪ Ability to monitor study sites independently, according to protocol monitoring guidelines, SOPs, GCPs and ICH applicable guidelines ▪ Full understanding of Safety Management, with particular focusing on SAE reporting, processes for reports and narrative s production and follow-ups ▪ Good planning, organization and problem solving abilities ▪ Excellent communication and interpersonal skills ▪ Good analytical and negotiation skills ▪ Good capabilities in written communications ▪ Excellent knowledge of English, both spoken and written ▪ Good capability of smart working and Team in remote interactions ▪ Good capability to work in a matrix environment Preferred: At least one year of experience in related fileds (i.e. clinical, pharmaceutical, laboratory, basic research, data analysis, data management, medical/technical writings)
Internal Relations	▪ INCIPIT Clinical Study Manager and Clinical Trial Assistant (within the Coordinating Center) ▪ INCIPIT Administrative Project Manager (within the Coordinating Center) ▪ INCIPIT local operational and administrative representatives (allocated to each Member of the Consortium) ▪ INCIPIT legal office ▪ INCIPIT GDPR advisor ▪ Functions/Departments of OPBG (Ospedale Pediatrico Bambin Gesù) who are involved in clinical studies (Principal Investigators, sub-Investigators and team of clinical research-including Study Coordinators and/or Data Managers, Study Nurses, local Pharmacy, laboratories and diagnostics services) ▪ OPBG Regulatory Advisor and Technical-scientific secretariat of the Ethics Committee ▪ OPBG Information Technology Service (IT) ▪ OPBG Local Pharmacy ▪ OPBG Clinical Trial Center
External Relations	▪ Sponsors of clinical studies (Pharmaceutical Companies, Biotechnological Companies, Medical Devices Companies, Nutraceuticals Companies; Clinical Research Networks/Consortia/Foundations; patients associations) ▪ Contract Research Organization (CRO) delegated for the management of the study ▪ External Provider (centralized Vendors as Clinical Manufacturing Organization (CMO), Centralized Laboratories, Services Providers of data management and statistics, etc.) ▪ Hospital functions involved in clinical studies (Principal Investigators, sub-Investigators and team of clinical research--including Study Coordinators and/or Data Managers, Study Nurses, local Experimental Pharmacy, laboratories and diagnostic services, Legal Offices, Administrative Offices, Technical Services Offices ▪ Ethics Committees/Regulatory authorities (for national and global studies) ▪ National Hubs, within the c4c frame ▪ Regulatory Authority (for national and global studies) in case of inspection