JOB DESCRIPTION

	Position title: Clinical Trial Assistant
Line Manager	Coordination Center of INCIPIT (key reference roles: Trial Operational Coordinator and Senior Scientific Manager)
Purpose of the Job	Supporting the Coordinating Center Team management of the activities of the Consortium, such as (but not limited to): • Organization of the operational activities allocated under the direct responsibility of INCIPIT relevant to the management of clinical studies (.i.e. medical writing, regulatory start-up, study/project management, monitoring, data management, statistics, PhV, etc) • Organization of the periodic and extraordinary INCIPIT Board of Directors and General Assembly • Reinforcement of INCIPIT infrastructure (dedicated working groups, GDPR organization, etc) • Management of INCIPIT financial/business structure • 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 provide administrative support to the general activities handled by the INCIPIT Coordinating Center Team, in terms of: ▪ Financial tracking (including, but not limited to invoicing, finalization of Work Orders, ad hoc contracts, tracking of the administrative activities of the NHs involved in the c4c projects/studies) ▪ Tracking of the agendas of pre-defined meetings/commitments and organization of ad hoc meetings, as per specific Team involvement ▪ Finalization of the meeting minutes, as requested and their distribution ▪ General management of calls, e-mails, costs notes and travels (this latter when applicable) ▪ Distribution of materials to Operative Team, Study Teams and or Scientific Teams ▪ Support the activities of INCIPIT Working Groups, as requested ▪ Support of interactions with local INCIPIT referee, also to retrieve specific information (such as, but not limited to: enrolment updates in clinical studies, missing documentation, meeting arrangements, etc.) In terms of regulatory activities: ▪ To support the internal CRAs and/or the Clinical Study Manager in performing the regulatory mapping for a clinical study/clinical project ▪ To supervise the internal regulatory resource in performing any regulatory submission and in maintaining the contacts with the National Hubs involved in c4c studies or other committed studies /activities

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	▪ To 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) ▪ To perform directly any regulatory submission (when requested by the Sponsor) and maintain contacts with Regulatory Authorities and/or Ethics Committees. In terms of operational activities: ▪ To support INCIPIT CRA and/or Clinical study Manager (CSM) in performing the pre- Feasibility and Feasibility Processes, directly or committed as per specific agreements with Networks, Sponsors and CROs ▪ To support the INCIPIT Coordinating Center Team in coordinating the bridging activities with the c4c NH Pv RP and the NH Lead Pharmacist/s ▪ To support INCIPIT CRA and/or Clinical study Manager 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 supervise the set-up, organization and maintenance of clinical study documentation (e.g. Main Study Files -including ISF, TMF and pharmacy Binders, etc.) according to Sponsor and/or CRO SOPs, including preparation for internal/external audits, final reconciliation and archival. If requested, to set-up, organize and maintain directly the clinical study documentation, according to Sponsor and/or CRO SOPs ▪ To support the CSM and CRA (either INCIPIT or external) to prepare and maintain study updates (either through managing platforms or tools developed ad hoc- Clinicl Study Management Systems-CTMSes) and to monitor the related costs progression (study budget management) ▪ To specifically bridge for ordering/dispatch and tracking of trial materials (e.g. diary cards, lab supplies, drug supplies) managed by the allocated Study Team Responsibles or co-ordinate directly such activities, to as appropriate ▪ To co-ordinate document translation, if required ▪ To assist INCIPIT Clinical Study Manager/CRA and Project Team with Investigator Meetings/ Kick-off Meetings coordination, activities preparation and to support with meeting minutes finalization.
Professional Background and Experience	▪ High School Diploma or Scientific Degree in Science ▪ Research or health care related academic or work experience ▪ From 3 to 5 years of experience in Clinical Trials coordination and or Clinical Development activities and a minimum of one (I) year of administrative experience (or equivalent training)
Technical Competencies	▪ Knowledge of GCPs and of Regulatory/ethics obligations for clinical trials/clinical development management ▪ Good Knowledge of the main Office software (Word, Excel, Power Point, etc.) ▪ Capability to get quick familiarity with CTMSes ▪ Basic knowledge of quality systems and quality assurance
General Competencies	▪ Good Knowledge of English, both spoken and written ▪ Good organizational skills, ability to manage multiple tasks and meticulous attention to detail ▪ Good time management skills ▪ Good written and verbal communication skills ▪ Ability on team working ad in particular good capability to work in a matrix environment

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Internal Relations	▪ INCIPIT Clinical Study Manager and CRA (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