Contatta

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Competenze principali

Pharmaceutical Industry
Clinical Trials
Clinical Development

Languages

Italiano (Native or Bilingual)
Inglese (Professional Working)

Ilaria Gentile

Clinical Trial Lead presso PSI CRO AG
Aprilia

Esperienza

PSI CRO AG

7 anni 5 mesi

Clinical Trial Lead

settembre 2018 - Present (3 anni 4 mesi)

support of site contractual start-up and budget negotiations; supervision of the preparation, collecting and reporting on project status updates; preparation of investigator newsletters; coordination and supervision of the safety information flow; monitoring of project timelines and patient enrolment; management and reporting on Key Performance Indicators; participation in monitoring and evaluation of team members' performance; coordination of the project team, acting as primary or secondary contact for the project team; participation in Project Review Meetings; participation in the development and update of project planning documents, essential study documents, and project manuals/ instructions; coordination of study-specific and corporate tracking systems maintenance; oversight of site selection and startup process; IP-REDs collection & approval process; establishing of communication lines within the project team; identification and escalation of resourcing issues; preparation of presentations and training; ensuring team compliance with project-specific training matrix; field training of team members tailored to the project needs; site initiation, routine monitoring, and close-out visits; oversight of investigator and site payments; oversight of CRF data retrieval/ upload and monitoring and the query resolution process; ensuring that sites are timely supplied with study medication and other study materials; support of the project team with the preparation for study audits/ inspections and resolution of audit/ inspection findings; QA visits to sites; participation in establishment and supervision of other in-process project controls; review of site visit reports and ensuring that standards for monitoring and reporting are met; oversight of proper TMF and OSF maintenance; support in preparation of initial and follow up Regulatory and Ethics Committee submissions and notifications; participation in feasibility research

Senior CRA

maggio 2017 - settembre 2018 (1 anno 5 mesi)

study start-up, clinical monitoring and site management activities to verify protection of trial subjects' rights, safety and well-being, data quality and compliance with the protocol, ICH GCP, regulatory and PSI/ Sponsor specific requirements; participation in site audits and other types of QC visits; CAPA development and implementation

Clinical Research Associate
agosto 2014 - maggio 2017 (2 anni 10 mesi)

site selection, initiation, routine monitoring and close-out visits conduct and reporting; site management; project-specific training of investigators and site teams; management of communication between sponsor and sites; monitoring of patients' enrollment at site level; ensuring S/AE and protocol deviations proper reporting and follow up; ensuring proper accountability and reconciliation of Investigational Product(s) and clinical supplies; review of essential documents and study OSF/PMF; source data verification; participation in site audits; support of IP-REDs packages preparation, as well as regulatory and ethics committee submission packages preparation; maintenance of study-specific and corporate tracking systems at site level; facilitation of documents, records, and laboratory supplies flow between trial sites and the Central/Regional Lab/Central Reviewer; ensuring ongoing evaluation of quality at site level; ensuring compliance with ICH GCP, regulatory and PSI/Sponsor specific requirements.

PRA Health Sciences
CRA 2
luglio 2013 - luglio 2014 (1 anno 1 mese)

L.N Age Srl
Clinical Research Associate
ottobre 2009 - luglio 2013 (3 anni 10 mesi)

site selection; site initiation; site close-out; site routine monitoring; CRF review and source data verification; sites and vendors communication; regulatory authorities communication (primary contact for communication with AIFA Italian Regulatory Agency); ethic committee communication; site management; visit reporting; S/AE processing and follow-up; feasibility support; client communication; training of site staff; training and mentoring of project team; study document review/preparation, ensuring compliance with national regulations, GCP, protocol and procedures; EDC; audit preparation, participation and follow-up; review and preparation of SOP and internal procedures

Grifols

Stagista

marzo 2009 - luglio 2009 (5 mesi)

- Theoretical sessions on the laws and authorizations required to perform clinical trials on medical products for human use in accordance with the good clinical practice.
- Practice sessions on clinical trial projects.
- Monitoring visits.
- Cooperation to prepare medical literature in particular with regard to haemostatic defects in human

Formazione

Università Cattolica del Sacro Cuore

Master's degree, Clinical and Pre-clinical drug development · (2010 - 2011)

Università degli Studi Roma Tre

Laurea, Biologia · (2001 - 2007)