

Position: Clinical Project Manager

Context: The Clinical Project Manager is a member of the Clinical Development Organization. The Clinical Development Organization designs and carries out clinical trials in humans, to prepare filing data for submissions to health authorities, and to support the market potential.

Main responsibilities: Coordination of activities related to the design, setup, execution and reporting of clinical trials in order to ensure the execution of these trials are according to international scientific and quality standards as well as ISA's objectives in terms of quality, timelines and budget.

Main activities:

- Provide input to the clinical development plan of ISA's products
- Prepare clinical trial specific project plans including budget and timelines
- Initiate/coordinate all actions necessary for the execution of clinical trials, including:
 - protocol writing
 - site selection and evaluation
 - contract management
 - selection and management of all third party organizations/vendors (CRO, central labs)
 - Clinical trial applications/IND
 - Study drug availability, shipment, accountability, destruction
 - Coordinate datamanagement, statistics and reporting of clinical trials
- Provide input to Quality Assurance in order to set up and maintain a quality system that ensures compliance of ISA's clinical development activities to international quality standards (GCP and others if applicable)

Interactions: Members of the Clinical Development Organization, including Regulatory Affairs, Manufacturing, Program Management, Quality Assurance and Medical.

Requirements:

- Minimally a Bachelors degree in preferably a life-science education
- Over 5 years experience in the management of clinical trials in humans, of which at least 2 years in a comparable position, preferably experience in managing international multicenter trials
- Experience in selection and management of third party vendors
- Excellent English writing and speaking skills
- Team player, willing to take on all necessary responsibilities needed to successfully deliver to the goals of ISA

Apply to:

ISA Pharmaceuticals BV, att. to Johan Frieling, Niels Bohrweg 11-13, 2333 CA Leiden.
Or by email: info@isa-pharma.com