JOB OFFER
JULY 2, 2018

enterome
bioscience

Clinical Project Manager

TASKS

1. End-to-end management of international clinical and translational study
2. Manage CRO on writing of studies documents (protocols, monitoring guide, consent forms, ... based on guidance from Head of Medical Dev't
3. Co-lead with Data manager the eCRF development by CRO
4. Privileged interlocutor of the CRO: current communication, organisation and conduct of teleconference and follow-up meeting projects,
5. Regular monitoring of the progress of the study, recruitment, indicators and deliverables (together with Head of clinical operation and medcial when required)
6. Identification and assessment of risks and problems, implementation and follow up of an action plan
7. Manage preparation of packages and local submissions of study documents (IRBs, Ethics Committees)
8. Ensure appropriate involvement of Data Manager for Data monitoring
9. Provide budget forecasts to Project Team and manage activities vs. budget
10. Organize logistics, investigator meetings, investigator training, site initiation and closure, etc
11. Participate in feasibility assessments
12. Negotiate quality agreements (with Legal support) and manage CRO AQ incl. audits

DIPLOMA'S / DEGREES

Science degree (Biology, Medicine, Pharmacy ...) followed by a training in clinical research

EXPERIENCES

- 5-8 years in clinical Project Management experience.
- 5+ yrs in biotech or biopharma industry, small/start-up environment preferred.
- Must have previous experience working within gastric phase 2-3 Clinical trials
- Strong experience managing clinical trials fully outsourced as well as managed directly
- Demonstrated proficiency with ICH/GCP guidelines

OTHER SKILLS

Languages:	French and English, others languages appreciated
Computer:	Office Pack
Other:	Multi-tasking, autonomous, shows initiative and must have strong leadership