Deputy Head of Quality, Clinical & Regulatory Affairs

Organization

FIND is an international non-profit organization based in Geneva, Switzerland, dedicated to R&D activities to expand and accelerate access to new diagnostic technologies, and to build global capacity for diagnostic testing for poverty-related diseases in low- and middle-income countries. FIND's vision is a world where diagnosis guides the way to health for all people. The FIND team is devoted to driving the development, clinical trialing, and early implementation of innovative diagnostic solutions that can have a high impact on patient care and disease control in low-resource settings.

Summary

The Clinical Trial Unit (CTU) at FIND was established in 2018 to provide internal teams with support for their clinical development programmes. CTU services include project management, trial design, QA/compliance oversight, risk-based monitoring, data management, statistical analysis, report writing and biobanking. CTU operates in accordance with ICH GCP. You will be acting as Deputy Head of Quality, Clinical & Regulatory Affairs within CTU and support diagnostics clinical trials/studies across multiple disease programmes, including malaria/fever, hepatitis C, neglected tropical diseases, emerging threats, AMR, and tuberculosis. This role reports to the Head of Quality, Clinical & Regulatory Affairs.

Responsibilities

The specific activities will include but not be limited to:

1. Providing functional expertise and strategic regulatory support to teams defining regulatory pathways for products in FIND's portfolio
2. Working with disease programmes in designing clinical evidence trials that meet requirements for marketing authorization and/or global policy endorsements, and demonstrating studies supporting in-country implementation or roll-out
3. Collaborating with Trial Managers, Project Managers and Clinical Officers to ensure that clinical trial activities meet the acceptable quality standards for diagnostic tests, as defined by customer requirements and in accordance with applicable regulations, international standards and guidelines
4. Assessing potential safety/medical device incident issues and determining reporting requirements to manufacturing partners.
5. Maintaining and improving the CTU quality management system so as to ensure that projects which involve human subject research are conducted in conformance to ICH GCP E6 R2 guidelines, with a focus on the rights, well-being and safety of study/trial participants and data integrity
6. Tracking issues against risks to determine effectiveness of the risk management system
7. Tracking and reporting CTU key performance indicators to senior management
8. Tracking lessons learnt at trial closure and performing trend analysis
9. Assisting teams with trial site feasibility, assessment and selection as well as vendor/CRO selection.
10. Providing support for trial start-up activities, including review of contracts, development of trial governance processes, Gantt charts, protocols, informed consent forms, case report forms and the eTMF.
11. Developing risk-based monitoring plans and performing competency assessments of monitors in the field
12. Hosting external audits of manufacturing partners and working with the teams to ensure any findings are addressed in a timely manner
13. Managing complaints handling, non-conformance, review Corrective and Preventive Action plans

14. Training staff in the management and conduct of clinical trials, as well as relevant GxP topics, CTU policies and procedures
15. Assisting with grant applications and M&E reporting
16. Engaging with a diverse array of stakeholders from private industry, consultants, WHO and health authorities.
17. Managing a small, motivated team

Education, knowledge and skill requirements

- Passion for the need and importance of new diagnostics for poverty-related diseases
- Advanced degree in Health or Life Sciences, or equivalent
- At least 8+ years of experience in a similar role in or supporting the *in-vitro* diagnostics (IVD) industry
- Ability to lead regulatory assessments of marketing claims drawing from IVD Regulatory Affairs experience
- In-depth knowledge of FDA and IVDR regulatory pathways, knowledge of regional or country-level regulatory and policy guidelines, ISO 13485 as well as sound understanding of product development including clinical trials/GCP and how they affect the regulatory approval timeline in different territories
- Experience overseeing and conducting clinical trials to include protocol design/development, site feasibility assessments, CRF design, project management, reference testing, monitoring and report writing.
- Experience in Quality Management, to include QA/QC, KPIs, competency assessments, SOP writing, GCP auditing, hosting external audits and regulatory inspections
- Experience working with CTMS/eTMF/eQMS systems and electronic data capture.
- Experience working in low- and middle-income countries.
- Strong knowledge of ISO 13485:2016, GXP, FDA and EU regulations including the IVDR.
- Strong analytical skills to drive complex regulatory decisions in an area with a lot of regulatory uncertainties
- Excellent interpersonal skills to interface with health authorities, manufacturers, suppliers, auditors and inspectors
- Effective communication, people and project management skills, including the ability to write well
- Fluent in spoken and written English; French, Spanish are a plus
- Ability to work in a dynamic, matrix environment with constantly changing priorities and little/no oversight
- Comfortable dealing with high pressure; pragmatic approach to problem solving with a high level of risk tolerance

To apply

Please send a motivation letter, a CV (maximum 2 pages) and three references to hr@finddx.org by **29 March 2019**

(But don't wait until the deadline! We will start screening right away and if we find the right person, we will stop searching.)

Please note that only applicants meeting the profile requirements will be personally contacted. Applications sent by recruitment agencies will not be considered