국제백신연구소 Clinical Operations Department 에서 Researcher를 모집합니다.

\* 채용 기관 및 부서

- 기관 : 국제백신연구소

- 부서 : Clinical Operations Department

\* 주요 업무

1. Provide Support in Research Projects:

- Provides supports to principal investigator/project team on study design and development of study protocols and study related documents (e.g., ICF, IAF, DCs…), standard operating and GXP procedures in provision of technical guidance

- Participates in the selection of study vendors for assigned studies

- Coordinates internal and external clinical operations activities of assigned study team

- Proactively identifies project risks and resolves with supervision from clin ops manager

- Collaborates with Clinical site coordinator to ensure clinical sites and investigators are conducting studies in compliance with local requirements, ICH-GCP guidelines, and study protocol

- Conducts Clinical Operations activities i.e. develops study related document, prepares regulatory documents submission, and monitors submission of project-related institutional review board (IRB)-documents

- Prepares, coordinates, and monitors Clinical trial supplies and shipments

- Communicates with the Manufacturer to ensure the quality of IP and IP handling including arrangement of IP shipment, monitoring its delivery under the required condition, and overseeing the IP handling procedures as per agreement

- Maintains the essential documents for the sponsor i.e. Trial Master File and periodically reviews and performs gap analysis between Sponsor File and Investigator Site File with the CRA (if applicable)

- If requires, writes and reviews monitoring report and Site visit report to assure that the oversight activities are performed and documents properly

- Oversees the clinical sites’ adherence to the regulatory and approved protocols through review of monitoring and audit reports, communicates with investigators, study site personnel, CRAs and other CRO/designee personnel

- Oversees the CRO’s activities to support the IVI project or study team

2. General Duties and Functions

- Contributes to the development of MOP and SOPs with Clinical Ops Manager and Project Lead, as required

- Proactively coordinate the regular Project Team meetings, conference calls and Minutes of Meeting including follow-up of action items.

- Proactively coordinate the CAPA responses in a timely manner, as needed

- Provides support in coaching, and training new members

- Develops monitoring tools and department initiatives, as needed

- Other assignment, as required

\* 자격 요건

- 최종 학력 : 석사 (Pharmacy, Nursing, Bio-medical related)

- 경력 : 경력 (in Clinical Operations)

\* 근무 조건

- 근무 시간 : 주 40시간 (오전 9시 ~ 오후 6시)

- 근무 형태 : 정규직

- 급여 조건 : 회사 내규에 따름

\* 채용 절차

- 서류 전형 및 면접 전형 : 면접 일정은 서류 합격자에 한해 개별 연락 예정

- 제출 서류 : 영문 이력서 (파일명은 ‘Researcher(Clinical Operations Department)\_영문성명’으로 작성)

- 지원 방법 : 홈페이지 접수 (https://www.ivi.int/careers/)

- 지원 기간 : 채용 마감 시까지