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FSP SSU (Taipei)

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Company: Fortrea

Location: Taipei

Category: other-general

As a leading global contract research organization (CRO) with a passion for scientific rigor and decades of clinical development experience, Fortrea provides pharmaceutical, biotechnology, and medical device customers a wide range of clinical development, patient access and technology solutions across more than 20 therapeutic areas. With over 19,000 staff conducting operations in more than 90 countries, Fortrea is transforming drug and device development for partners and patients across the globe.

The Study Start-Up Manager (SSU Manager) is responsible at country level for managing and conducting start-up activities in compliance with the procedures, documents, local and international guidelines such as ICH – GCP and relevant regulations.

The SSU Manager will prepare, review, track and manage site regulatory documentation at country and site level, and will maintain, review and report on site performance metrics.

The SSU manager works in close collaboration with the CRAs and the Local Study Team/Local Study Associate Director to ensure that study start-up activities and milestones are achieved in a timely and efficient manner.

Typical Accountabilities

Contribute to ensure that clinical and operational feasibility assessment of potential studies is performed to the highest quality.

Accountable for study start-up and regulatory maintenance being in charge with collection, preparation, review and tracking of documents for the application process;

Accountable for submission of proper application/documents to Regulatory Authorities and/or

IEC/IRB during start-up period.

Actively participates in Local Study Team (LST) meetings.

Update CTMS and other systems with data from study sites as per required timelines during the start-up period.

Follow up on outstanding actions with study sites during start-up period to ensure resolution in a timely manner.

Ensure timely collection/uploading of essential documents into the eTMF in accordance with ICH-GCP, SOPs and local requirements. Support QC checks performed by LSAD or delegate to ensure that all country and site level trial essential documents required by ICH-GCP prior to study start have been collected and verified for correctness, prior to setting sites ready to enrol, and in line with SOPs.

Provide regular information to Line Managers at country level on study and planned study milestones/key issues during the start-up period.

Provide feedback on any research related information including sites/investigators/competing studies that might be useful for the local market.

Support SMM in different initiatives (local, regional or global) as agreed with the SMM Line Management.

Upon local decision, additional responsibilities may include*:

Prepare, review and negotiate contracts with investigational sites being the primary point of contact for investigational sites to ensure the contracts are fully executed

Support site selection process by identifying and assessing potential sites/investigators

Accountable for continuing submission of proper application/documents to IEC/IRB and to Regulatory Authorities for the duration of the study.

Assist in initial forecasting for budget, study materials and drug supplies. Plan applicable local drug activities (local purchase or reimbursement)

EssentiaEducation, Qualifications, Skills and Experience

Bachelor degree in related discipline, preferably in life science, or equivalent qualification.

At least 2 years experiences in the role for regulatory/EC submission would be better.

Good knowledge of international guidelines ICH-GCP as well as relevant local regulations, basic knowledge of GMP/GDP

Basic understanding of drug development process

Good collaboration and interpersonal skills.

Good verbal and written communication skills.

Excellent attention to details.

Excellent understanding of Clinical Study Management and study start-up

Good negotiation skills.

Good ability to learn and to adapt to work with IT systems.

Fortrea is actively seeking motivated problem-solvers and creative thinkers who share our passion for overcoming barriers in clinical trials. Our unwavering commitment is to revolutionize the development process, ensuring the swift delivery of life-changing ideas and therapies to patients in need. Join our exceptional team and embrace a collaborative workspace where personal growth is nurtured, enabling you to make a meaningful global impact.

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