Vietnam Jobs Expertini®

Clinical Study Administrator - HCM

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Company: AstraZeneca

Location: Ho Chi Minh City

Category: other-general

Clinical Study Administrator - HCM

The ideal candidate is a passionate, self-motivated, and detail-oriented team player who is committed to the success of our customers. Then AstraZeneca might be the one for you!

About AstraZeneca and AstraZeneca Vietnam

AstraZeneca

AstraZeneca (LSE/STO/Nasdaq: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialization of prescription medicines in Oncology, Rare Diseases and BioPharmaceuticals, including Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. Please visit astrazeneca.com and follow the Company on Twitter @AstraZeneca.

AstraZeneca Vietnam

As a Foreign Invested Enterprise with over 550 members, AstraZeneca is investing into Vietnam 310 million USD from 2020 to 2030 with a focus on reducing the burdens of non-communicable diseases, developing local talent, and uplifting the domestic biopharmaceutical R&D and manufacturing capabilities.

Over the last three decades accompanying Vietnam’s sustainable development, AstraZeneca has run several impactful programmes in collaboration with the Government, Ministry of Health and healthcare partners to promote disease awareness, prevention and early detection. In recent years, AstraZeneca Vietnam has received several certificates of

merit from the Prime Minister and Minister of Health, for excellent contributions to Vietnam's vaccine diplomacy, fight against COVID-19 and advancement of cancer treatment and disease awareness. The company has also been recognized among Vietnam's Top 100 Best Places to Work (2018 – 2022) with various other industry awards from BritCham, EuroCham, and government agencies.

What you'll do

Short role description

The Clinical Study Administrator (CSA) assists in the coordination and administration of the study activities from the start up to execution and close out, and within the Local Study Team (LST) to ensure quality and consistency of interventional study deliverables to time, cost and quality objectives.

Typical Accountabilities

Assists in coordination and administration of clinical studies from the start-up to execution and close-out.

Collects, assists in preparation, reviews and tracks documents for the application process. Assists in timely submission of proper application/documents to EC/IRB and, where appropriate to Regulatory Authorities for the duration of the study.

Interfaces with Investigators, external service providers and CRAs during the document collection process to support effective delivery of a study and its documents.

Serves as local administrative main contact and works closely with the CRAs and/or the LSM for the duration of the study.

Operational responsibility for the correct set-up and maintenance of the local eTMF and ISF including document tracking in accordance with ICH- GCP and local requirements.

Ensures essential documents under their responsibility are uploaded in a timely manner to maintain the eTMF "Inspection Readiness".

Ensures that all study documents are ready for final archiving and completion of local part of the eTMF and supports the CRA in the close out activities for the ISF.

Contributes to the production and maintenance of study documents, ensuring template and version compliance.

Creates and/or imports clinical-regulatory documents into the Global Electronic Management System (e.g. ANGEL) ensuring compliance with the AstraZeneca Authoring Guide for Regulatory Documents.

Contributes to electronic applications/submissions by handling clinical-regulatory documents according to the requested technical standards i.e. Submission Ready Standards (SRS), supporting effective publishing and delivery to regulatory authorities.

Sets-up, populates and accurately maintains information in AstraZeneca tracking and communication tools (e.g. CTMS such as IMPACT, SharePoint, etc) and supports others in the usage of these systems (with the exception of countries where there is a specific role dedicated to set up and update the systems).

Prepares and/or supports contract preparation at a site level (with the exception of countries where there is a specific role dedicated to preparing site contracts).

Prepares/supports/performs Health Care Organisations (HCO)/Health Care Professionals (HCP) payments in accordance with local regulations.

Manages and contributes to coordination and tracking of study materials and equipment.

Coordinates administrative tasks during the study process, audits and regulatory inspections, according to company policies and SOPs.

Leads the practical arrangements and contributes to the preparation of internal and external meetings e.g. study team meetings, Monitors' meetings, Investigators' meetings. Liaises with internal and external participants and/or vendors, in line with international and local codes.

Prepares, contributes to and distributes presentation material for meetings, newsletters and web-sites.

Responsible for layout and language control, copying and distribution of documents. Supports with local translation and spell checks in English to/from local language, as required.

Responsible for printing and distribution of documents such as letters and meeting minutes, and for handling and archiving of study/country related e-mails.

Interfaces with Data Management Centre and/or Data Management Enablement representatives to facilitate the delivery of study related documents/material.

Ensures compliance with AstraZeneca's Code of Ethics and company policies and procedures relating to people, finance, technology, security and SHE (Safety, Health and Environment).

Ensures compliance with local, national and regional legislation, as applicable.

Education, Qualifications, Skills and Experience

Essential

High school/Secondary school qualifications (*), that supports skills and capabilities of the position and ensures successful conduct of responsibilities and appropriate interactions with internal and or external customers.

Previous administrative experience preferably in the medical/ life science field.

Proven organizational and administrative skills.

Computer proficiency.

Good knowledge of spoken and written English.

(*) to be adapted to local country market needs.

Desirable

Further studies in administration and/or in life science field are desirable (*)

Working knowledge of the Clinical Study Process and an understanding of the range of working procedures relating to it, together with an understanding of the ICH-GCP guidelines.

Ability to develop advanced computer skills to increase efficiency in daily tasks.

Good verbal and written communication.

Good interpersonal skills and ability to work in an international team environment.

Willingness and ability to train others on study administration procedures.

Excellent organization and time management skills, excellent attention to detail, and ability to multi-task in a high-volume environment with shifting priorities.

Team oriented and flexible; ability to respond quickly to shifting demands and opportunities.

Integrity and high ethical standards.

Key stakeholders and relationships

Internal (to AZ or team)

Local Study Team including Local Study Managers and CRAs

Line Manager (ADSMM and local SMM LT)

Clinical Quality Manager

Global Study Teams

Local Regulatory Affairs

Enablement functions

* Medical Department personnel if CSA supports local studies (as per agreement by CH/CD and Medical Director)

External (to AZ)

Investigators and site personnel

Study related vendors

ECs/ IRB

Regulatory Authorities

Why AstraZeneca?

At AstraZeneca, we're dedicated to being a Great Place to Work. Where you are empowered to push the boundaries of science and fuel your entrepreneurial spirit. There's no better place to make a difference to medicine, patients, and society. An inclusive culture that champions diversity and collaboration, and is always committed to lifelong learning, growth, and development. We're on an exciting journey to pioneer the future of healthcare.

What will you get?

We provide driven packages and benefits for proficient and qualified candidates; a winning dream team and colleagues who share ONE values, ideas, and goals.

So, what's next?

If you are already inspiring yourself to join our dream team, we can't wait to hear from you.

If you are ready to bring new insights and fresh thinking to the table, Brilliant! We have one seat available, and we hope it's yours.

If you're curious to know more then please take initiative to We encourage your application.

Where can I find out more?

Visit our website www.astrazeneca.vn

Follow us on LinkedIn www.linkedin.com/company/astrazeneca/

Contact us via

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26-thg 3-2024

Closing Date

29-thg 6-2024

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