Study Start-Up Lead

Job ID
REQ-10036651
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Resumen

The Study Start-Up (SSU) Lead plans and executes global SSU activities to ensure timely trial document and task completion to enable country HA (Health Authorities) and Ethics Committee submissions and site activation to meet ambitious recruitment plans. The Study Start-Up Lead works collaboratively with other key CTT members and leads the SSU Team (CTT sub-team) comprised of the country SSU Management, Vendor Management, Regulatory, Grants and Contracts, Translations, Document Management, Clinical Supplies, and others as needed to accelerate study, country, and site activation.

About the Role

Key responsibilities

- Contributes SSU insights to the development of the trial Operational Execution Plan (OEP) and aligns the SSU plan and strategy accordingly as reflected in SSU systems, milestones and dashboards with Study Leader/Clinical Trial Team (CTT).
- Configures and ensures proper trial-specific set-up of SSU systems (e.g., Expected Document Lists, eTMF, milestones, tasks, personnel, vendors, languages/translations, confirmed and back-up countries, CTMS (Clinical Trial Management System), enrollment plan, vendor management tool, site contracting and budgeting tool, ICF template tool, etc.)
- Prepares global SSU planning and leads SSU Team (CTT sub-team) from kick-off through completion of SSU (all countries and 95% sites enrolling or as defined per trial)
- Implements global aspects of protocol and OEP amendments, activates and oversees country implementation of amendments as determined per trial and in conjunction with Study Leader.
- Ensures timely collection global trial level document readiness (including vendor and IMP (INVESTIGATIONAL MEDICINAL PRODUCT)) and collection into eTMF as necessary for country health authority and Ethics Committee submission and site activation
- Supports the Vendor Program Manager (VPM) as needed to ensure timely global vendor activation and HA submission documents
- Ensures Protocol and ICF (Informed Consent Form) global trial template is ready for country usage as necessary including translations
- Drives transparency of timelines of global SSU deliverables with SSU Managers to ensure country alignment and efficiency
- Directs the Study Grants Expert for investigator grant plan/fair market value assessment initiation and finalization of country site budget and contract template readiness in conjunction with protocol timelines
- Global accountability of timelines, accuracy, and quality of global TMF (Trial Master File) documents in study start-up to ensure TMF inspection readiness
- Provide proactive oversight and risk management for SSU team activities to achieve start-up timelines

and quality execution, proposing and implementing corrective actions where appropriate, according to Novartis standards and local and international regulations
- Collaborates with GCS (Global Clinical Supply) to ensure coordination and readiness of global clinical supply
- Ensures proper hand-off of activities applicable to the Study Leader and other roles as necessary
- Ensures the use and date completeness/accuracy of applicable technology platforms during SSU
- Enables country Study Start-up Managers to drive timely start-up activities from country allocation to “Ready to Enroll” within assigned trial
- Provides oversight and support to country Study Start-up Managers as needed to ensure that study start-up activities are conducted and completed to plan, including set-up and usage of tools/systems, timely delivery of SSU deliverables (e.g. IRB/IEC submission packages, Informed Consent review, local submission package for submission to IRB/IEC, CTA (Clinical Trial Application) Hub (Europe: acc. to new EU-CTR) as well as Health Authorities and adherence to process standards.
- Supports the VPM as needed to ensure global vendor activation and site readiness in collaboration with to meet site activation timelines/plan.
- Ensure global deliverables to enable site initiation readiness is in place for initial drug release
- Ensures global and country budget (TCF (Trial Commitment Forms)) processes and approvals support SSU activities and timelines

Essential Requirements

- Minimum 2 years' experience in clinical operations in a role that oversees (project management) and/or with monitoring clinical trials
- Minimum 1 years of contribution to and accomplishment in all aspects of conducting clinical trials (e.g., planning, executing, reporting and publishing) in a global/matrix environment in pharmaceutical industry or a contract research organization
- Proven ability to effectively engage and lead associates from varying backgrounds and functions within dispersed and highly matrixed organizations.
- Excellent communication, influencing and negotiating skills
- Good knowledge of Good Clinical Practice, clinical trial set-up design and global drug development process
- Demonstrated effective influencing and negotiation skills at all levels.
- Data and Digital expertise. Experience working with electronic databases, clinical and/or project management planning and reporting and analytics systems
- Data and timeline driven, Willingness and ability to champion the use of new technology

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