Clinical Operations Program Associate Director

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Irlande

Résumé

The Clinical Operations Program Associate Director (COPaD) is accountable for the oversight, coordination and development of early viability assessments, global feasibility assessments (pre-IMB and trial feasibility), recruitment projections and allocation strategies for the assigned trials and programs. As a key member of the Global Clinical Operations (GCO) sub-team, the COPaD will provide precise oversight and ensure alignment with the overarching strategy and GCO operational position adding directly into the feasibility strategies. The COPaD scope of activities include pre-IMB project feasibility and/or early viability assessment, trial feasibility assessment, validation and refinement of trial allocation strategy, including scenario planning and risk management, and any re-feasibility assessments, as applicable. Drives operational excellence through overall project milestone management and system requirements, process improvement and knowledge sharing across clinical indication(s)/program(s) within Development Unit. Navigates in a matrix environment and adjusts quickly to business needs. Leads analyses of external and internal data to validate and refine strategic allocation of assigned trials and programs enabling accurate overall decision making by Clinical Operations Program Head (COPH) and GCO sub-team. Partners with COPH and is a key member of the GCO sub-team ensuring delivery of the Operational Execution Plan (OEP) by applying agile and product-oriented ways of working. Displays full allegiance to the COPH and GCO sub-team and is accountable for high quality and timely contributions to the OEP. Key partner to the Feasibility Managers and Clinical Research Medical Advisors (CRMAs) to ensure overall quality and delivery of feasibility assessments from initial site identification until final site allocation

About the Role

Major accountabilities:

- Accountable for leading and conducting the end-to-end feasibility process starting from early viability assessments as well as pre-IMB and trial feasibilities and for developing strategic allocation, site selection and recruitment plans scenarios for the assigned programs and trials.
- As part of the GCO sub-team, remains as the point of contact for assigned program and trial feasibilities, leading the multidisciplinary feasibility teams to develop, validate and refine allocation strategy, including timelines, scenarios, and risk mitigation plans. Identifies and resolves events in the indication landscape that represent operational risks for the execution of clinical trials within the given indication/program. Leads integration of regional and local indication strategies within global execution plans.
- Partners closely with the country feasibility team to align on the end-to-end quality of feasibility product
- Key contributor to the Operational Execution Plan:
  - Collection and analysis of internal and external data (i.e. local treatment standard of care, available treatment options approved/reimbursed, local prevalence and access to targeted population) thorough analysis of clinical intelligence data describing the indication landscape including scientific and

epidemiology data, competitive intelligence, treatment paradigms and potential site partners globally, from external and internal research data sources including analysis of historical data related to site performance (data quality, start-up cycle time, patient enrollment), based on the clinical intelligence package received from the Health Insights Manager and other data sources
- Defines an optimal geographic country footprint and proposed sites for participation in a clinical trial and supports COPH & GCO sub-team on final site allocation.
- Executes the feasibility process by developing feasibility assessment/survey, coordinates execution of feasibility, evaluates prospective sites on their operational and medical capability to conduct the study, and provides a thorough analysis and summary of feasibility outcome to the GCO sub-team
- Develops and proposes risk management strategies for clinical trial(s) highlighting feasibility related operational risks and mitigation actions for program and trial feasibility and allocation.
- In collaboration with the COPH, GCO sub-team and feasibility team, defines the final allocation and selected countries and sites
- Performs ongoing analysis and reassessment of feasibility against recruitment throughout the lifecycle of the trial, including re-allocation or corrective actions when needed and alignment with regional teams

- Responsible for the creation and maintenance of patient enrollment forecast, at study levels
  - Based on prior experience and analytics, works with COPH to define the patient enrollment scenario that can be flexible based on the study objectives or meet specific study requirements (i.e., enrollment objectives, endpoints, cost, timelines, TPP).
  - Curates and analyzes relevant data to define a projected patient rate of recruitment and the enrollment timeline, that factors in site activation roll-out for a clinical study
  - Maintains the patient enrollment forecast from a strategic perspective and is responsible for providing a re-forecast patient enrollment model to adjust for new influence factors (i.e., change in drug landscape, protocol amendment, increased screen failure rate, delayed timelines, etc.).
- Ensures alignment of feasibility and allocation strategy and seamless start up planning with COPH, Study Start-Up Lead and feasibility teams
- Improves and develops tools and processes for early viability assessments, feasibilities, recruitment projections, etc.
- May participate in cross-functional strategic initiatives.

Requirements:

- Bachelors in life science/healthcare required; Advanced degree or equivalent education/degree in life sciences/ healthcare preferred (PhD/MD/ PharmD/ Masters).
- ≥ 5 years of pharmaceutical clinical drug development experience recommended (with ≥3 years in planning/execution global clinical trials recommended)
- Strong understanding of all aspects of clinical drug development with particular emphasis on clinical trial design, trial execution, and strong knowledge about the feasibility and allocation process of a program and/or study.
- Possess strong, resourceful research skills to locate unusual information and have capacity to develop a deep domain specific knowledge base.
- Understand the Clinical Trial matrixed process from research through post marketing phase IV, health authority guidelines, country challenges as well as sources for therapeutic area data.
- Demonstrated ability to collaborate across partner functions in a matrix environment, without direct reports, but able to coordinate the activities of others.
- Demonstrated experience in feasibility for global clinical trials.
- Has had success in identifying, proactively flagging, and resolving risks; experience with strategic scenario planning and management.
- Communicates effectively with leaders in a local/regional/global matrixed environment.

- Proven ability on strategic planning and managing operational challenges at global, regional, or country level.
- Good project management capabilities with demonstrated ability to problem solve and mediate complex issues.
- Strong ability to understand analytical data insights with proven ability to communicate background details and rationale.
- Thorough knowledge of the international aspects of drug development process, the international standards (GCP/ICH),health authority regulations, and clinical development process.
- Good understanding of global competitive landscape and implications on clinical development.
- Strong leadership and negotiation skills.
- Demonstrated strong presentation and diplomacy skills.

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