Clinical Operations Program Manager

Job ID
REQ-10024857
Ott 18, 2024
Svizzera

Sommario

Location: This position can based in Basel, Switzerland; Dublin, Ireland; Westworks, London, UK or Cambridge, MASS, US* (please note to apply for the US position please apply using the US requirement on our Careers site)

Hybrid

About the role:
The Clinical Operations Program Manager (COPM) will provide operational support for clinical development programs and trials where there are early viability, feasibility, allocation and site selection activities to deliver. The scope of activities for this key role will range from early viability, feasibility assessment, validation and refinement of allocation strategy, including scenario planning and risk management, and any re-feasibility assessments, as applicable.

About the Role

Your Key Responsibilities:

- Provide key support to conduct 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, in particular by providing:

- Preparation and coordination of briefing information, training resources and other materials
- Project planning support and follow-up / management of key deliverables
- Assist assembly of actions, output summary and minutes for follow-up tracking
- Lead aspects of the feasibility activity as needed – e.g., feasibility survey consolidation and analysis, review of data insights with feasibility teams, etc.

- Coordinate and manage the editing, technical support resolution and distribution of information gathering questionnaire for feasibility at trial level between sites, countries and global. Ensure feedback from feasibility assessment is addressed.
- Partner closely with the country feasibility team to align on the end-to-end quality of feasibility product
- Elaborate scenarios of geographic country footprint and proposed sites for participation in a clinical trial and supports COP(a)D, COPH a GCO sub-team on final site allocation.
- Contribute to the execution of the feasibility process by developing feasibility assessment/survey, coordinates execution of feasibility at country level, 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

- Contribute to the development of risk management strategies for clinical trial(s) highlighting feasibility-related operational risks and mitigation actions for program and trial feasibility and allocation.

Minimum Requirements:

- Minimum Bachelors' degree or Master's in life science/healthcare.
- Minimum of 3-5+ years of pharmaceutical clinical drug development experience
- 1+ year minimum of proven experience in planning/execution global clinical trials in a pharma and/or CRO environment
- 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 resourceful research skills to locate unusual information and have capacity to develop a domain specific knowledge base.
- Demonstrated experience in feasibility for global clinical trials.
- Proven success in identifying, proactively flagging, and resolving risks; experience with strategic scenario planning and management.
- Ability to understand analytical data insights with proven ability to communicate background details and rationale.

You'll receive:
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Accessibility and accommodation:
Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to inclusion.switzerland@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

*(please note that to apply for the US position please apply using the US requirement on our Careers site)

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