

Clinical Ops Manager (Feasibility)

Job ID
REQ-10024844
Oct 29, 2024
USA

Summary

Clinical Operations Program Manager

The ideal location for this role is our East Hanover, NJ site but remote work may be possible (there may be some restrictions based on legal entity). Please note that this role would not provide relocation as a result. If associate is remote, all home office expenses and any travel/lodging to specific East Hanover, NJ site for periodic live meetings will be at the employee's expense. The expectation of working hours and travel (domestic and/or international) will be defined by the hiring manager. This position will require minimum travel (1-2 trips per year).

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:

- Bachelors' degree in life science/healthcare.
- 3+ years of pharmaceutical clinical drug development experience
- 1+ year of experience in planning/execution global clinical trials
- 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.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between \$130,000 - \$195,000/year; however, while salary ranges are effective from 1/1/24 through 12/31/24, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together?
<https://www.novartis.com/about/strategy/people-and-culture>

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Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Division

Development

Business Unit

Innovative Medicines

Location

USA

Site

East Hanover

Company / Legal Entity

U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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