

Clinical Operations Manager

Job ID
REQ-10036382
Ene 22, 2025
Irlanda

Resumen

The Clinical Operations Program Manager (COPM) is responsible for provide operational support for clinical development programs and trials where there Our Development Team is guided by our purpose: to reimagine medicine to improve and extend people's lives.

To do this, we are optimizing and strengthening our processes and ways of working. We are investing in new technologies and building specific therapeutic areas and platform depth and capabilities – all to bring our medicines to patients even faster.

We are seeking key talent, like you, to join us and help give people with disease and their families a brighter future to look forward to.

Apply today and we can thrive together!

This role will be based in Dublin, Ireland in a hybrid working approach.

About the Role

The Role:

Are you ready to become a Clinical Operations Manager? The successful incumbent will be responsible for providing operational support for clinical development programs and trials
You will assist in analysis of external and internal data to validate and refine strategic allocation of assigned trials, aligned with program allocation strategy, thereby enabling accurate overall decision making.
Partners with Clinical Operations Project Director and will be a supporting member of the GCO sub-team ensuring delivery of the Operational Execution Plan (OEP) by applying agile and product-oriented ways of working. You will be accountable for high quality and timely contributions to the OEP, partnering the Feasibility Managers and CRMAs to ensure overall quality and delivery of feasibility assessments from initial site identification until final site allocation.

Major accountabilities but not limited to:

- Supports the COP(a)D or the GCO sub-team 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.
- 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.

- Partners closely with the country feasibility team to align on the end-to-end quality of feasibility product
- May contribute 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 populations) through 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 enrolment), based on the clinical intelligence package received from the Health Insights Manager and other data sources
- Elaborates 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.
- Contributes 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
- Contributes 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.
- Supports the creation and maintenance of patient enrolment forecast, at study levels

Key performance indicators:

- Timely, efficient, and quality execution of activities in compliance with quality standards.
- Proactive operational planning with effective contingency and risk mitigation plans.

Your Experience:

- Degree in Life Sciences or related scientific discipline.
- More than 3 years of pharmaceutical clinical drug development experience is recommended
- Understanding of all aspects of clinical drug development with particular emphasis on clinical trial design and trial execution.
- Possess resourceful research skills to locate unusual information and have capacity to develop a domain specific knowledge base.
- Demonstrated ability to collaborate in a matrix environment.
- Demonstrated experience in feasibility for global clinical trials.
- Communicates effectively with colleagues in a local/regional/global matrixed environment.
- Good project management capabilities with demonstrated ability to problem solve and mediate issues.
- Ability to understand analytical data insights with proven ability to communicate background details and rationale.
- Strong skills in MS Office Suite.
- Fluent in English

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>

Commitment to Diversity & Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve.

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Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: <https://talentnetwork.novartis.com/network>

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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

División

Development

Business Unit

Innovative Medicines

Ubicación

Irlanda

Sitio

Dublin (NOCC)

Company / Legal Entity

IE02 (FCRS = IE002) Novartis Ireland Ltd

Alternative Location 1

London (The Westworks), Reino Unido

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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