Study & Site Operations Feasibility Manager

Job ID
REQ-10041073
fév 21, 2025
Royaume-Uni de Grande-Bretagne et d'Irl. du Nord

Résumé

Accountable for the oversight and coordination of program and study level (re-)feasibility assessments in the country, in collaboration with program and/or trial feasibility teams, in compliance with Novartis processes, Good Clinical Practice (GCP), International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use (ICH) and regulatory requirements.

This position is key to establish good communication and professional relationships with clinical investigators and company stakeholders on country/cluster/hub/global level. Closely collaborates with Study & Site Operations and relevant medical/clinical functions to ensure successful allocation, realistic country targets, recruitment according to planned timelines, early identification of risks and opportunities as well as potential delays and mitigation plan.

About the Role

About the Role:

- Single point of contact for communication between Clinical Operations Program Managers / Clinical Operations Program Head, country/extended country group Study & Site teams and
- Coordinates the feasibility activities on country/extended country group level by ensuring:
  - Site identification and selection, trial feasibility evaluation
  - Collates/validates the list of potential sites by utilizing internal and external data (e.g. historical data, individual knowledge within local Study & Site Team and relevant medical/clinical functions, internal and external databases)
  - Manages the study specific feasibility questionnaire and sends to all participating sites together with any supporting documentation, if applicable
  - Follows up with sites to ensure questionnaires are answered and any additional feedback is obtained
  - Assess the clinical feasibility of implementing a clinical trial protocol based on regional/local medical practice using physician interviews, local databases (RWE, payer data, patient association feedback, etc.) and analysis of the competitive environment
  - Enters feedback into global database if applicable (e.g. CLIP)
- Collects, analyses, and interprets data to provide comprehensive proposals and timelines for country / extended country group allocation of clinical programs and assigned trials
- Responsible for early identification for potential risks and opportunities as well as potential synergies and back-up strategies within the country group.
- Closely collaborates with the Study & Site team to ensure fast clinical trial start up, recruitment according to planned timelines, early identification of potential delays and robust recruitment mitigation plan. Co-

own start-up phase and the recruitment plan for development clinical trials with the Study & Site Operations.

Key Performance Indicators:

- Timely submission of feasibility data
- Performance against study commitments at the country level, including delivery of studies per defined number of patients and quality
- Delivery of study milestones esp. in startup phase in adherence to prevailing legislation, GCP, Ethical Committee and SOP requirements

Your Experience:

- Scientific degree and advanced degree with a minimum of 5 years' experience in clinical development experience gained in the pharmaceutical. Industry clinical trial experience and/or project management, is preferable
- Capable of leading in a matrix environment, without direct reports and working cross-border
- Ability to manage a study from the medical/clinical perspective, and a demonstrated capability to problem solve and mediate complex-clinical / medical / operational issues
- Agility to move fast across different therapeutic areas and indications
- Strong project management capabilities
- Demonstrates a knowledge of how to adequately review and read a protocol to understand specifics of study design and answer questions regarding the trial
- Applies a detailed understanding of the drug in question to provide medical context as it relates to disease processes, populations, and standards of care
- Ability to assess the feasibility of implementing the protocol based on regional medical practice and sound understanding of the overall clinical development plan

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

Join our Novartis Network:

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

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

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

Join our Novartis Network: 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

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

Division
Development
Business Unit
Innovative Medicines
Emplacement
Royaume-Uni de Grande-Bretagne et d'Irl. du Nord
Site
Field Force (England / Wales)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Functional Area
Recherche & Développement
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

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

Job ID
REQ-10041073

Study & Site Operations Feasibility Manager

Apply to Job

Source URL: *https://www.adacap.com/careers/career-search/job/details/req-10041073-study-site-operations-feasibility-manager*

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards

4. https://www.novartis.com/about/strategy/people-and-culture
5. https://talentnetwork.novartis.com/network
6. https://www.novartis.com/careers/benefits-rewards
7. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Field-Force-England--Wales/Study--Site-Operations-Feasibility-Manager_REQ-10041073-1
8. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Field-Force-England--Wales/Study--Site-Operations-Feasibility-Manager_REQ-10041073-1