NOVARTIS

Central Integrated Scientific Review Committee Lead

Job ID
REQ-10021368
Sep 18, 2024
Royaume-Uni de Grande-Bretagne et d'Irl. du Nord

Résumé

When we put our heads together, we can do brilliant work. And when we do brilliant work, we can achieve remarkable things for patients as we positively transform healthcare. We are looking for a Central Integrated Scientific Review Committee Lead.

The Central Integrated Scientific Review Committee Lead (C-ISRC Lead) plays a key role in the review and approval of clinical documents across therapeutic areas in Development. Key to the role is following documents from C-ISRC submission to finalization, including meeting preparation, meeting management and documentation via minutes for completeness, consistency and process adherence.

In collaboration with the C-ISRC Chair and Co-Chair (Clinical Development Head) you will act as project manager in the review cycle and associated activities for high-quality and efficient C-ISRC meeting. Key outcomes are high-quality concept sheets, protocols and clinical development plans. Key systems include Collaborative Authoring Tool (CAT), and various tracking systems. Periodic participation in process/guidance review, best practice identification, trainings, C-ISRC process overview presentations, testing of new collaboration tools and other team projects is encouraged.

This role can be based in London, UK or Dublin, Ireland.

About the Role

Your responsibilities will include;

- Manages C-ISRC Review process for approximately 100+ clinical documents each year
- Ensures appropriate C-ISRC documentation and meeting management
- Assists in the development of high-quality protocols and other clinical documents via addressing C-ISRC processes/workflow related questions, and training and guidance as appropriate
- Works with various systems and trackers to ensure smooth C-ISRC workflow (includes CAT, Please Review, Document Management System, etc.); may work on system improvement as appropriate
- Serves as back-up to fellow C-ISRC Leads and may attend C-ISRC meetings to take minutes or co-facilitate the sessions
- Manages timely key data entry to create reports from appropriate systems and facilitate tracking of key metrics for the C-ISRC Office
- May assist in audits and inspection readiness as needed/related to C-ISRC process/documentation
- Supports other C-ISRC and Clinical Development projects and activities as appropriate (e.g. updating

guidance, contributing to trainings and best practice sharing, etc.)

Minimum requirements

- Minimum Bachelor’s degree in science; Advanced degree, or equivalent, in science or healthcare preferred.
- 5+ years’ experience in pharmaceutical industry
- Strong knowledge of clinical drug development process, including trial design, GCP, regulatory processes, and clinical project management
- Working knowledge of IT systems and trackers, including Document Management System
- Excellent interpersonal, communication, presentation and meeting management skills
- Advanced medical/scientific writing and communication skills
- Ability to influence wide variety of stakeholders in a matrix environment.

Why Novartis? Our purpose is to reimagine medicine to improve and extend people’s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

You’ll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards Commitment to Diversity and Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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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Development
Business Unit
Innovative Medicines
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Royaume-Uni de Grande-Bretagne et d'Irl. du Nord
Site
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Alternative Location 1
Dublin (Novartis Corporate Center (NOCC)), Irlande
Functional Area
Recherche & Développement
Job Type

Full time
Employment Type
CDI
Shift Work
No
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