

CISR Committee Lead

Job ID
REQ-10021368
Oct 14, 2024
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.

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.

Role Requirements

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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Division

Development

Business Unit

Innovative Medicines

Location

Ireland

Site

Dublin (NOCC)

Company / Legal Entity

GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Functional Area

Research & Development

Job Type

Full time

Employment Type

CDI

Shift Work

No

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