Associate Director, Plain Language Trial Summaries

Job ID
REQ-10063668

10月 06, 2025

United Kingdom

摘要

Step into a pivotal leadership role at Novartis as Associate Director, Plain Language Trial Summaries (PLTS), where you will champion transparency and patient engagement in clinical research. You will ensure sustainable compliance with EU Clinical Trial Regulations and Novartis standards, leading the design, preparation, translation, and dissemination of patient-friendly trial summaries. Your expertise will drive process improvements, regulatory alignment, and cross-functional collaboration, making a meaningful impact on patient understanding and public trust in clinical research.

Location: London, UK / Barcelona, Spain / Dublin, Ireland #LI-Hybrid

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

About the Role

Responsibilities:

- Lead and matrix manage delivery of plain language trial summaries, ensuring quality and compliance across therapy areas and development phases.
- Oversee eligibility assessment and disclosure of trial summaries, interpreting and representing trial data accurately in clinical registries.
- Address, resolve, and escalate internal and external queries related to plain language trial summaries.
- Prepare Novartis for new EU CTIS and UK requirements by standardising plain language trial summary templates.
- Develop, test, and implement metrics reporting for trial summary postings, updating work instructions to align with regulatory changes.
- Stay current with global policies and regulations, harmonising Novartis transparency processes and standards.
- Identify barriers to process alignment, create implementation plans, and partner with IT to optimise compliance and harmonisation.
- Represent Novartis to internal and external stakeholders, maintaining effective relationships with global leaders and functional teams.
- Create and maintain SOPs and work practices for trial summaries, managing audits and supporting enhancements to digital tools.
- Lead financial contracts and outsourcing processes for trial summaries, implementing best practices and sharing lessons learned.

Essential for the role:

- Minimum bachelor ' s degree, preferably in the sciences.
- Over 10 years ' experience in the pharmaceutical industry, including statutory disclosure, trial registration, and results preparation.
- Proven expertise in clinical research development and cross-functional drug development deliverables.
- Experience in writing protocols and clinical summary reports across multiple indications and therapy areas.
- Mastery of clinical trial management systems (CTMS) and document management systems (DMS); ability to use Clinical Trial Application System (CTA).
- Demonstrated leadership in clinical research, project management, medical writing, or related areas.
- Ability to influence and work successfully in cross-divisional, multicultural matrix environments.
- Fluent English (oral and written).

Desirable for the role:

- Process and performance orientation, with ability to develop and implement improved processes and report on performance metrics.
- Strong problem-solving, communication, and time management skills, with adaptability to changing environments.

Commitment to Diversity & 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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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

部门
Development

Business Unit
Universal Hierarchy Node

地点
United Kingdom

站点
London (The Westworks)

Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Alternative Location 1

Barcelona Gran V í a, Spain

Alternative Location 2
Dublin (NOCC), Ireland

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

Apply to Job

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