Senior Manager Plain Language Trial Summary

Job ID
REQ-10038778
fév 13, 2025
Royaume-Uni de Grande-Bretagne et d'Irl. du Nord

Résumé

Contribuer, avec une surveillance appropriée, à tous les aspects pertinents des activités d'essais cliniques mondiaux afin d'obtenir les résultats de l'étude dans les délais, le budget, la qualité/conformité et les normes de rendement. Peut diriger des aspects spécifiques d'essais cliniques mondiaux. Membre principal de l'équipe des essais cliniques, contribue à l'excellence opérationnelle par l'amélioration des processus et le partage des connaissances et/ ou fournit des contributions au processus de développement clinique.

~Applicable à Clinical Scientific Expert II
L'expert scientifique clinique II (CSE II) fournit un soutien clinique et scientifique à toutes les phases d'une étude clinique sous la direction du (A)CD(M)D conformément aux processus de Novartis, aux BPC de l'ICH et aux exigences réglementaires. Ce rôle applique les principes d'excellence de l'examen des données cliniques et identifie les informations sur les données cliniques pour s'assurer que les données sont scientifiquement plausibles et pour identifier les tendances, les signaux et les risques associés aux critères d'évaluation des essais et à la sécurité des patients. Le CST II est un membre clé de l'équipe d'essais cliniques (CTT). De plus, le CST II appuie/dirige des documents ou des activités au niveau du programme selon les attributions.

About the Role

The Senior Manager has primary accountability to independently provide project management and execution to ensure quality plain language trial summary postings are prepared, translated and disseminated to investigational sites in compliance with the EU Clinical Trial Regulations and the Novartis Position on Clinical Study Transparency across NIBR-TCO, Global Drug Development, Global Medical Affairs and local affiliates.

Major Accountabilities

- Manage multiple plain language trial summaries through the entire process ensuring timelines are maintained. PLTS process steps include gathering required documentation for vendor contract preparation, arranging and/or leading PLTS review meetings, reviewing PLTS documents, ensuring study lead and medical lead review of PLTS, overseeing PLTS content finalization, PLTS translation and distribution by vendors and archiving of key documents in the document management system. Responsible for coordination of communications between vendor and the clinical team.
- Interpret, discuss and ensure appropriate trial data from the CSR is accurately represented in the plain language trial summary. Independently address and resolve questions received from the therapy areas and country representatives. Identify potential timeline, quality, or resource issues. Negotiate and implement solutions or escalate to CDO management when necessary for assistance.
- Review and maintain the Clinical Disclosure Office PLTS book of work in the Clinical Disclosure Office Analysis and Reporting Tool (CDO ART) and ensure the PLTS request for proposal process is complete

for submission to the vendors.
- Responsible for staying current with the global plain language trial summary work practice & health authority regulations to ensure harmonization of Novartis transparency processes and standards. Identify barriers to alignment of processes and discuss within the PLTS CDO team an implementation plan.
- Independently organize and conduct routine client trainings within NIBR-TCO, Global Drug Development, Global Medical Affairs and local affiliates to drive quality and compliance and organizational alignment to changing disclosure requirements.
- Independently represent Novartis to internal and external stakeholders. Develop and maintain effective working relationships with global and country multidisciplinary leaders, such as Study Leads, M.D.s, medical writers, statistical programmers, and vendor project management teams.
- Participate in the review of updates to the plain language trial summary work practice and other CDO SOPs and preparation for external inspections & internal audits.
- Participate in the assessment, preparation and review of monthly Plain Language Trial Summary (PLTS) disclosure metrics as requested.
- Apply a continuous improvement mind set ensuring best practices are shared continually driving to deliver the most productive processes.

What you will bring to the role:

- Minimum bachelor's degree in a scientific discipline preferred
- Greater than 5 years pharmaceutical industry experience with proven knowledge in cross functional aspects of drug development, experience in writing protocols/clinical summary reports/disclosure results or writing publications, exhibit copy, experience in multiple clinical indications and/or therapy areas desired. Prior experience using clinical trial management systems (CTMS) and document management systems (DMS). Proficiency in Microsoft office applications.
- Proven leadership skills in a position within Clinical Research Development, Data Management, Project Management, Medical Writing, Clinical Disclosure or related areas.
- Ability to influence and successfully work within a complex cross divisional matrix across different cultures. Previous experience leading or working within a multidisciplinary team in a matrix environment
- Strong negotiation & conflict resolution skills, well organized, focused on results/compliance, strong planning, tracking, problem solving and decision-making skills. Ability to adapt to changing environment.
- Proficiency in Good Clinical Practice, knowledge of clinical trial regulations and clinical trial designs.
- Ability to adapt to a changing external environment
- Fluent English (oral and written).

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

Commitment to Diversity & Inclusion:

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

Accessibility and accommodation:

Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because

of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in any order to receive more detailed information about essential functions of a position, please send an e-mail to inclusion.switzerland@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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

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Business Unit
Universal Hierarchy Node
Emplacement
Royaume-Uni de Grande-Bretagne et d'Irl. du Nord
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London (The Westworks)
Company / Legal Entity
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Employment Type
CDI
Shift Work
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Senior Manager Plain Language Trial Summary

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