

Japan Clinical Trial Lead

Job ID

393841BR

Juli 10, 2024

Japan

Summary

-Contributes, with appropriate oversight, to all relevant aspects of global clinical trial(s) activities to deliver study outcomes within schedule, budget, quality/compliance and performance standards. May lead specific aspects of global clinical trial(s). Core member of the Clinical Trial Team. -Applicable to Clinical Scientific Expert I The Clinical Scientific Expert I (CSE I) provides clinical and scientific support through all phases of a clinical study under the guidance of the (A)CD(M)D in compliance with Novartis processes, ICH GCP and regulatory requirements. This role applies the principles of clinical data review excellence and identifies clinical data insights to ensure data is scientifically plausible and to identify trends, signals and risks associated to trial endpoints and patient safety. The CSE I is a core member of the Clinical Trial Team (CTT) and may support program level activities as assigned.

About the Role

Major accountabilities:

- Implementing issue resolution plans; -Assist with program level activities (e.g., tracking of program - Managing interactions with relevant line functions including data management, drug supply management, clinical development and/or Novartis Country Pharma Organizations; -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt - Distribution of marketing samples (where applicable)

Key performance indicators:

- Timely, efficient and quality execution of assigned trials and trial related activities within budget, and in compliance with quality standards.
- Proactive operational planning with effective contingency and risk mitigation plans.
- Applicable for Clinical Scientific Expert I: -Performing clinical data review and insights consistently and accurately which meets the Novartis quality standards, timelines, and is inspection ready.
- High quality contributions to study documents (e.g. protocol, ICF, clinical sections of CTA) -Clearly demonstrates Novartis Values and Behaviors (i.e. Innovation, Quality, Collaboration, Performance, Courage and Integrity).

Minimum Requirements:

Work Experience:

- Operations Management and Execution.
- Collaborating across boundaries.
- Project Management.

- Cross Cultural Experience.

Skills:

- Clinical Research.
- Clinical Trial Protocol.
- Clinical Trials.
- Data Integrity.
- Learning Design.
- Lifesciences.
- Risk Monitoring.
- Trends Analysis.

Languages :

- English.

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Institutes for BioMedical Research (NIBR)
Business Unit
Pharma Research
Standort
Japan
State
Hokkaido
Site
Head Office (Japan) (Pharmaceuticals)
Company / Legal Entity
JP05 (FCRS = JP005) Novartis Pharma K.K.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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List of links present in page

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