

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 (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 Clincial 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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TEst Hello

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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