Clinical Development Scientist

Job ID
REQ-10093210

十一月 23, 2026

India

摘要

-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 IThe 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:

- Perform high-quality clinical data review and identify clinical data insights through patient level review and trends analysis, supporting Interim Analysis, Database and Post Lock activities and facilitate resolution of clinical data issues. Collaborate with relevant line functions to enhance the quality of clinical data review/insights with an emphasis on subject safety and eligibility, data integrity, trend identification, analysis and remediation, and identification of cases for medical review.
- Contributes to the development the Data Review/Quality Plan (DRP/DQP) and data review strategy, ensuring that protocol-level deviations, eligibility criteria, study assessments & other aspects of the protocol are implemented consistently across the study.
- In conjunction with the relevant line functions, may contribute to Case Report Form (CRF) development, and support the implementation of data capture tools.
- Contribute to and facilitate data review process improvements e.g. identification of delinquent/redundant reports and/or implementation of innovative data analysis processes and tools.
- May contribute (in collaboration with relevant line functions) to the development of study-level documents, including clinical sections of key regulatory documents, such as Investigator's Brochures, briefing books, safety updates and submission dossiers. In collaboration with relevant line functions, review/write clinical trial documents for study CSR activities, and publications.
- May support pharmacovigilance activities (e.g., reviewing/contributing to aggregate reports/patient narratives, attendance of Safety Monitoring Meetings (SMT)), if required.
- Produce training materials and provide training to iCTT. Support/present at study level meetings (Investigator Meetings, Data Monitoring Committee (DMC) meetings or others), as required.
- Develop subject matter expertise (disease area knowledge, clinical data review tools and/or processes).
- Contribute to line function initiatives, local and/or global education and process development projects, as required.

Essential Requirements

- Advanced degree in life sciences/healthcare (or clinically relevant degree) is required. Master's, PharmD, MPharm, PhD, MBBS, BDS, MD strongly preferred.
- 1-2 years scientific, strategic and operational experience in planning, executing, reporting, and publishing clinical studies in industry or Academia, or 3-4 years in Clinical Operations/Clinical Scientific role
- Intermediate knowledge of planning, executing, reporting, and publishing global clinical studies in a pharmaceutical company or contract research organization or similar experience with an academic research institution
- Good knowledge of Good Clinical Practice and drug development processes
- Strong scientific knowledge in at least one therapeutic area (e.g., understanding of basic mechanisms of diseases and associated symptoms, standard of care/treatment, scientific endpoints & clinical outcomes)
- Knowledge of principles of clinical data collection and reporting; ability to use systems and tools (e.g., EDC systems, Excel, etc.) for data collection, analysis and reporting. Experience in Rave and/or OC-RDC is an advantage.
- Analytical / computational background; ability to detect data trends and escalate as appropriate. Demonstrates knowledge and application of statistical analysis methodology and good medical / scientific writing skills
- Ability to collaborate across boundaries for shared success and resolve issues or understand

when to escalate

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

Benefits and Rewards: Learn about all the ways we ' ll help you thrive personally and professionally. Read our handbook (PDF 30 MB)

部门
Development

Business Unit
Development

地点
India

站点
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Research & Development

Job Type
Full time

Employment Type

Regular

Shift Work
No

var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId: "kalturaplayer6b048a172acb7334476997", provider: { widgetId: "10m7rm1pm", partnerId: "2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause: false, muted: false, loop: false }, sources: { options: {}, startTime: 0 }, disableUserCache: "true", plugins: {}, sources: { options: {}, startTime: 0 }, ui: { showCCButton: false, settings: { showQualityMenu: true, showSpeedMenu: false }, components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [{ presets: ['Playback', 'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get: kPlayer.ui.components.Remove }] } }; // Check and add plugins only if they exist if (kPlayer.plugins["download"]) { config.plugins.download = { disable: true }; } if (kPlayer.plugins["transcript"]) { config.plugins["playkit-js-transcript"] = { position: "right", // Default: bottom;('left', 'right', 'top', 'bottom') to enable transcript. expandMode: "over", // Default: alongside;('alongside', 'hidden', 'over') expandOnFirstPlay: false, showTime: true, downloadDisabled: false, printDisabled: false, disable: true }; } if (kPlayer.plugins["preventSeek"]) { config.plugins.preventSeek = { preventSeekForward: false, preventSeek: false }; } config.plugins.floating = { disable: true }; if (kPlayer.plugins["navigation"]) { config.plugins.navigation = { position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; } if (kPlayer.plugins["hotspots"]) { config.plugins['playkit-js-hotspots'] = { disable: true }; } if (kPlayer.plugins["moderation"]) { config.plugins['playkit-js-moderation'] = { disable: true }; } if (kPlayer.plugins["info"]) { config.plugins['playkit-js-info'] = { disable: true }; } if (kPlayer.plugins["share"]) { config.plugins.share = { disable: true }; } config.ui.uiComponents = []; if (kPlayer.plugins["googleAnalytics"]) { config.plugins.googleTagManager = {}; config.plugins.googleTagManager.customEventsTracking = {}; config.plugins.googleTagManager.containerId = 'GTM-57RJQ5'; config.plugins.googleTagManager.customEventsTracking.custom = []; config.plugins.googleTagManager.customEventsTracking = { preset: { coreEvents: true, UIEvents: false, playlistEvents: false, castEvents: false } }; }

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