NOVARTIS

Senior Specialist, Patient Safety

Job ID
REQ-10093026

十一月 23, 2026

India

摘要

-Monitors and audits the company ' s drug, biologics or medical devices surveillance program including the intake, evaluation, processing and follow-up on adverse reports. Participates in the resolution of any legal liability and in complying with government regulations. Ensures accurate receipt, maintenance and assessment against product labeling. Reports events or reactions as required by regulatory agencies including adverse events data from clinical trials, spontaneous or solicited sources, periodic and experience reports. May provide trending and safety signal detection and assessment. Supports all clinical trial activity and post marketing.

About the Role

Major Accountabilities:

- Manage the collection, processing, documentation, reporting and follow-up of all adverse event reports for all Novartis products from Clinical Trials, Non-interventional Studies, Patient

Oriented Program (POPs)s, Literature, Spontaneous Reports, and any other source of information.
- Transcribe, translate, and enter data from source documents into safety systems accurately and consistently with focus quality and on timeliness. When case processing activities are externalized, liaise with the respective External Service Providers to ensure Novartis Procedures' compliance.
- Manage reporting/submission/distribution of safety reports/updates/information (e.g., SAE, SR, IN/SUSAR, PSUR, Biannual SUSAR Listing, DSUR) to Local Health Authorities (LHA) and/or clinical operations in cooperation with other Country Organization Departments.
- Develop, update, and implement local procedures to ensure compliance with Patient Safety global procedures and national requirements.
- Interact and collaborate with other departments (such as Medical Affairs, Marketing, Patient Engagement, etc.) to ensure that any projects/ initiatives involving safety data collection (POPs, DEAs, SM/SML, etc.) follow the Novartis vigilance requirements.
- Management and distribution of vigilance clauses to other departments (such as Legal, Procurement, etc.) to be included in local agreements if necessary.
- Advice the owners of local contracts/ agreements with impact in the vigilance system, about the vigilance provisions to be included, as required per Novartis procedures and/or applicable regulations.

- Ensure compliance with the commitments disposed in the contracts/ agreements. Ensure the applicable local contracts/ agreements are tracked in the respective Pharmacovigilance Agreement SharePoint. Ensure any significant departure from the standard vigilance templates are communicated and endorsed by the global PS Alliance group

Essential Requirements

- Knowledge of national and international regulations for pharmacovigilance
- Knowledge of pharmacological and medical terminology
- Good communication and interpersonal skills
- Quality and results oriented and Project management skills
- 2 years as Patient Safety Specialist (preferred)
- Health Care Sciences Professional (e.g., Medical Doctor, Nurse, Pharmacist), life science degree or equivalent training and experience.

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
Other

地点
India

站点
Mumbai (Head 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: "kalturaplayer6b04cef83f6c4796514505", 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 } }; }

// Ensure the global player registry array always exists, regardless of embed type. window.kalturaPlayerVideos = window.kalturaPlayerVideos || []; try { var thumbEmbedPromise = thumbnailEmbed({config, mediaInfo: {entryId: "1dgfvmafo"}}); // thumbnailEmbed() returns a Promise that resolves with the player instance // when the user clicks the thumbnail. Use .then() to capture the player directly. thumbEmbedPromise .then(function(player) { window.kalturaPlayerVideos.push(player); // Notify kaltura datalayer.js that a new player is ready so it can // attach custom event listeners immediately, regardless of when // the user clicked the thumbnail relative to page load. document.dispatchEvent(new CustomEvent('kalturaPlayerReady', { detail: { player: player } })); }) .catch(function(error) { console.error(error); }); } catch (e) { console.error(e.message) }

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