

SSO Study Start-up Manager

Job ID
REQ-10074010

3月 23, 2026

Denmark

摘要

The SSO Study Start-Up Manager is accountable for study planning, SSU activities and activation deliverables of assigned projects in compliance with Novartis processes, GCP/ICH and regulatory requirements in Denmark. Leads all SSU activities of assigned projects in close collaboration with SSO Feasibility Manager and SSO Site Partnership Manager as well as the global study team. Act as primary back-up and deputy of the country manager.

About the Role

Accountabilities:

- Supports country SSU strategy in close collaboration with SSO Study Start-Up Team Lead, SSO Country Head Portfolio / SSO Cluster Head Portfolio
- Collaborates with SSO Country / SSO Portfolio Team Leads and global study team to ensure SSU timelines and deliverables are met according to country commitments

- Accountable for timely start-up activities from country allocation until Green Light (ready to initiate site millstone) in assigned projects
- Ensures close collaboration with local IRBs/IECs and Health Authorities, as applicable
- Ensures that study start-up activities are conducted and completed on time, including preparation of IRB/IEC submission packages and review of Informed Consent Forms
- Prepares and finalizes local submission package for submission to IRB/IEC, CTA Hub (Europe: acc. to new EU-CTR) as well as Health Authorities as applicable
- Coordinates timely response to deficiency letters in close collaboration with local and global stakeholders
- Accountable for timelines, accuracy, and quality of country TMF documents in study start-up to ensure TMF inspection readiness
- Ensures adherence to financial standards, prevailing legislation, ICH/GCP, IRB/IEC, Health Authority and SOP requirements
- Implements innovative and efficient processes which are in line with Novartis strategy
- Supports study feasibility in close collaboration with Feasibility Manager and Site Partnership Manager as well as the global study team
- Leads site selection in collaboration with Portfolio Team Lead and Clinical Project Manager if already assigned
- Oversees local vendor selection and performance as needed. Serves as main contact for quality/compliance issues in SSU phase, escalating as necessary
- Ensures sites are prepared for “Green Light” and ensures all documentation is in place for initial and subsequent drug release. Responsible for review and sign off of the site “Green Light”
- Oversees local SSU team activities in assigned studies to achieve start-up timelines and quality execution according to Novartis standards and local and international regulations
- Leads/chairs local SSU team meetings in assigned studies, participates in global study team meetings, as required
- Leads the development of country site initiation and patient enrolment plans together with SSU CRA, CPM and SSU Lead

Education:

- A degree in scientific or health discipline required and advanced degree with clinical trial experience and/or project management, is preferable

Languages:

- Fluent in both written and spoken English, local language as needed

Experience/Professional requirement:

- Minimum 5 years' experience in clinical operations in a role that oversees (project management) and/or with monitoring clinical trials
- Capable of leading in a matrix environment, without direct reports

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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

Denmark

站点

Copenhagen

Company / Legal Entity

DK06 (FCRS = DK006) Novartis Healthcare A/S

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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function adjustKalturaPlayer() { var deviceWidth = window.innerWidth ||
document.documentElement.clientWidth || document.body.clientWidth; var mediaElement =
document.getElementById("kalturaplayer69c6429d443ae697873629"); var mediaContainer =
mediaElement.closest('.nc-kaltura-media'); var originalWidth = "1200px"; var originalHeight = "674px";
var originalWidthValue = parseFloat(originalWidth); var originalHeightValue =
parseFloat(originalHeight); var mediaType = "video"; var isResponsive = false; // Get computed styles
of the container element. var parentStyles = window.getComputedStyle(mediaContainer); var
finalWidth = parseFloat(parentStyles.width); if (finalWidth < originalWidthValue) {
var config = { targetId:
"kalturaplayer69c6429d443ae697873629", provider: { widgetId: "10m7rm1pm", partnerId:
"2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause: false,
allowMutedAutoPlay: false, loop: false }, sources: { options: {}, startTime: 0 }, plugins: { download: {
disable: true }, "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 } }, ui: { showCCButton: false, settings: { showQualityMenu: true, showSpeedMenu: false },
components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [ { presets: ['Playback',
'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get:
KalturaPlayer.ui.components.Remove } ] } }; config.plugins.preventSeek = { preventSeekForward:
false, preventSeek: false }; config.plugins.floating = { disable: true }; config.plugins.navigation = {
position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; config.plugins['playkit-
js-hotspots'] = { disable: true }; config.plugins['playkit-js-moderation'] = { disable: true };
config.plugins['playkit-js-info'] = { disable: true }; config.plugins.share = { disable: true };
config.ui.uiComponents = []; 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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try { var kalturaPlayer = KalturaPlayer.setup(config); // Add the player to the global array. if (typeof
kalturaPlayerVideos !== 'undefined') { kalturaPlayerVideos.push(kalturaPlayer); } else { var
kalturaPlayerVideos = []; kalturaPlayerVideos.push(kalturaPlayer); } // Load the Player for other
media. kalturaPlayer.loadMedia({entryId: "1dgfvmafo"}); setTimeout(() => {
setupAutoPause(kalturaPlayerVideos); }, 500); function setupAutoPause(players) {
players.forEach((currentPlayer) => { currentPlayer.addEventListener('play', () => {
players.forEach((otherPlayer) => { if (otherPlayer !== currentPlayer && typeof otherPlayer.pause ===
'function') { otherPlayer.pause(); } })); }); }); } catch (e) { console.error(e.message) }

```



VIDEO

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

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