NOVARTIS

# SSO Study Start-Up Team Lead

Job ID
REQ-10020010
Ago 23, 2024
Ungheria

## Sommario

The SSO Study Start-Up Team Lead is accountable for the governance and oversight of a study start-up team in a standalone country or OPC (operating country). The SSO Study Start-Up Team Lead is supporting the country/OPC SSU strategy and prioritization in close collaboration with SSU/OPC Head and Country/OPC LT to deliver operational excellence of the GDD portfolio in compliance with Novartis processes, ICH/GCP and regulatory requirements.

## About the Role

### Study Start-Up Strategy

- Supports Study & Site Operations Country Leadership Team to identify innovative practices to optimize country operations and operational excellence, especially in terms of study start-up activities to increase performance, productivity, and business impact
- Seeks and evaluates external knowledge and best practices to enhance overall operational excellence of country trial operations
- Supports country SSU strategy in close collaboration with SSU/OPC Head and Portfolio Head/Portfolio Team Lead(s)
- Responsible for timely start-up activities from country allocation until site Green Light (ready-to-initiate-sites)
- Ensures close collaboration with local IRBs/IECs and Health Authorities, as applicable

### Allocation, initiation and conduct of trials

- Collaborates with Head Portfolio, SSO Portfolio Team Leads and global study team (Clinical Operations Program Head, Trial Lead) to ensure SSU timelines and deliverables are met according to country commitments
- Accountable for timelines, accuracy, and quality of TMF documents, including study start-up and ongoing TMF maintenance 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

### People and resource management

- Hiring, training, development, and retention of Study Start-Up associates
- Resource management and reporting of Study Start-Up associates
- Ensures associates have the required level of skills to successfully set-up and execute studies with high

quality and according to business objectives
- Manages and oversees productivity targets per defined objectives, and serves as an escalation point for Study Start-Up functions

**Activities & Interfaces**

- Interfaces with global trial execution organization through Global SSU managers for all portfolio deliverables.
- Partners with SSU CRAs to drive all trial level start up activities including essential document collection.

**Requirements:**

**Education:**

- A degree in scientific or health discipline required

**Languages:**

- Fluent in both written and spoken English
- Fluent in both written and spoken country language

**Experience/Professional requirement:**

- Minimum 5 years' experience in clinical operations and planning
- Proven leadership capabilities and experience (with or without direct line management responsibilities).
- Understanding of all aspects of clinical drug development with particular emphasis on trial set-up, execution, and monitoring
- Thorough understanding of the international aspects of drug development process, including strong knowledge of international standards (GCP/ICH), health authorities (FDA/EMA), local/national Health Authorities regulations and Novartis standards

**Competencies:**

- Strong capability in working in a global/country matrix environment
- Proven successful leadership of teams (with or without direct reports), preferably with experience in working with international teams
- Strong interpersonal, negotiation and conflict resolution skills

**Why Novartis:**
Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reac h our ambitions. Be a part of this
mission and join us! Learn more here: https://www.novartis.com/about/strategy/people and culture

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

**Join our Novartis Network** :

If this role is not suitable to your experience or career goals but you wish tostay connected to hear more about Novartis and our career opportunities, join the Novartis Network here:

https://talentnetwork.novartis.com/networkhttps://talentnetwork.novartis.com/network

**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

**Join our Novartis Network:** Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

**Benefits and Rewards:** Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Divisione
Development
Business Unit
Innovative Medicines
Posizione
Ungheria
Sito
Budapest
Company / Legal Entity
HU02 (FCRS = HU002) Novartis Hungary
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

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

iframe{ width: 100%; margin-top: 3rem; } @media screen and (max-width: 767px){ iframe{ height: 30vh !important; } } @media screen and (min-width: 768px){ iframe{ height: 34vh !important; } }
Job ID
REQ-10020010

## SSO Study Start-Up Team Lead

Apply to Job

---

**Source URL:** *https://www.adacap.com/careers/career-search/job/details/req-10020010-sso-study-start-team-lead*

**List of links present in page**

1. https://talentnetwork.novartis.com/networkhttps://talentnetwork.novartis.com/network
2. https://www.novartis.com/about/strategy/people-and-culture
3. https://talentnetwork.novartis.com/network
4. https://www.novartis.com/careers/benefits-rewards
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Budapest/SSO-Study-Start-Up-Team-Lead_REQ-10020010-1
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Budapest/SSO-Study-Start-Up-Team-Lead_REQ-10020010-1