NOVARTIS

Study Start Up Lead

Job ID
REQ-10024090

10月 03, 2024

Ireland

摘要

When we put our heads together, we can do brilliant work. And when we do brilliant work, we can achieve remarkable things for patients as we positively transform healthcare. We are looking for a Study Start Up Lead to join our global team.

The Study Start-Up (SSU) Lead plans and executes global SSU activities to ensure timely trial document and task completion to enable country HA (Health Authorities) and Ethics Committee submissions and site activation to meet ambitious recruitment plans. The Study Start-Up Lead works collaboratively with other key CTT members and leads the SSU Team (CTT sub-team) comprised of the country SSU Management, Vendor Management, Regulatory, Grants and Contracts, Translations, Document Management, Clinical Supplies, and others as needed to accelerate study, country, and site activation.

This role can be based in Dublin, London or Hyderabad offices in a hybrid model with expectation to be in the office 12 days/month.

About the Role

Your responsibilities will include;

- Contributes SSU insights to the development of the trial Operational Execution Plan (OEP) and aligns the SSU plan and strategy accordingly as reflected in SSU systems, milestones and dashboards with Study Leader/Clinical Trial Team (CTT).
- Configures and ensures proper trial-specific set-up of SSU systems (e.g., Expected Document Lists, eTMF, milestones, tasks, personnel, vendors, languages/translations, confirmed and back-up countries, CTMS (Clinical Trial Management System), enrolment plan, vendor management tool, site contracting and budgeting tool, ICF template tool, etc.).
- Prepares global SSU planning and leads SSU Team (CTT sub-team) from kick-off through completion of SSU (all countries and 95% sites enrolling or as defined per trial)
- Implements global aspects of protocol and OEP amendments, activates and oversees country implementation of amendments as determined per trial and in conjunction with Study Leader.
- Ensures timely collection global trial level document readiness (including vendor and Investigational medicinal product and collection into eTMF as necessary for country health authority and Ethics Committee submission and site activation.
- Supports the Vendor Program Manager as needed to ensure timely global vendor activation and Health Authority submission documents.
- Ensures Protocol and Informed Consent Form global trial template is ready for country usage as necessary including translations.
- Drives transparency of timelines of global SSU deliverables with SSU Managers to ensure country alignment and efficiency.
- Directs the Study Grants Expert for investigator grant plan/fair market value assessment initiation and finalization of country site budget and contract template readiness in conjunction with protocol timelines.

Minimum requirements

- Advanced degree or combination Bachelor ' s Degree with equivalent experience
- A degree in scientific or health discipline required and an advanced degree with clinical trial experience and/or project management
- Fluent English, oral and written
- Experience in clinical operations in a role that oversees (project management) and/or with monitoring clinical trials
- Contribution to and accomplishment in all aspects of conducting clinical trials (e.g., planning, executing, reporting and publishing) in a global/matrix environment in pharmaceutical industry or a contract research organization
- Proven ability to effectively engage and lead associates from varying backgrounds and functions within dispersed and highly matrixed organizations.
- Excellent communication, influencing and negotiating skills
- Good knowledge of Good Clinical Practice, clinical trial set-up design and global drug development process
- Data and Digital expertise. Experience working with electronic databases, clinical and/or project management planning and reporting and analytics systems

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 reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards 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.

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

部门
Development

Business Unit
Innovative Medicines

地点
Ireland

站点
Dublin (Novartis Corporate Center (NOCC))

Company / Legal Entity
IE02 (FCRS = IE002) Novartis Ireland Ltd

Alternative Location 1
Hyderabad (Office), India

Alternative Location 2
London (The Westworks), United Kingdom

Functional Area
Research & Development

Job Type
Full time

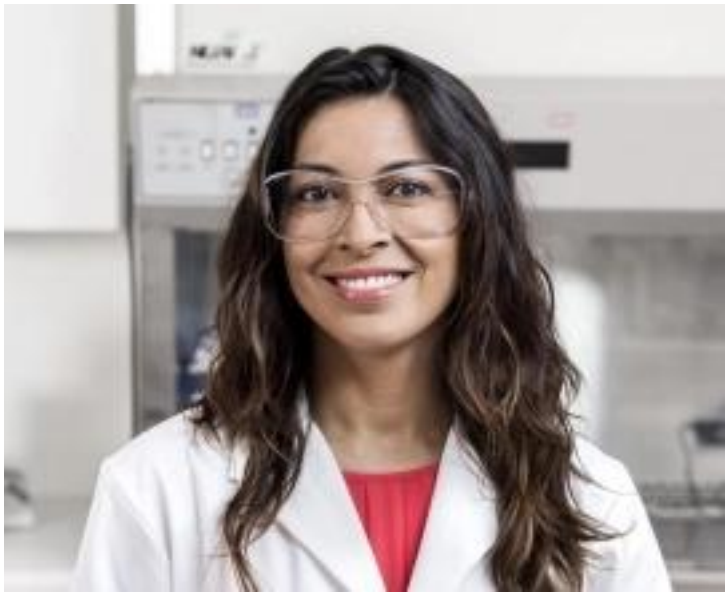
Employment Type
Regular

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-10024090

Study Start Up Lead

Apply to Job

Source URL:
https://prod1.novartis.com.cn/careers/career-search/job/details/req-10024090-study-start-lead

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
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/NovartisCareers/job/Dublin-Novartis-Corporate-Center-NOCC/Study-Start-Up-LeadREQ-10024090-1
6. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Dublin-Novartis-Corporate-Center-NOCC/Study-Start-Up-LeadREQ-10024090-1