NOVARTIS

# Senior Study Leader

Job ID
REQ-10041219
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Reino Unido

## Resumen

The Senior Study Lead will oversee budget and people allocation within assigned study/studies. Promotes operational excellence through process improvement and knowledge sharing across studies. Fosters an empowered, psychologically safe organization that can navigate a matrix environment, learns, and adjusts quickly to changing conditions and business needs. Accountable for resolution of study management operational issues and impediments within assigned study/studies.

This is a hybrid position with 12 days per month from the office in White City, London.

#LI-Hybrid

## About the Role

**Key responsibilities:**

- Leads the clinical trial team delivery of multiple medium to complex global studies and promotes learning, sharing, consistent performance, and operational excellence through an agile mindset, agile principles, and an agile team of teams model
- Acts as the CTT product owner with duties and responsibilities per the agile ways of working
- Guides planning and decision making at the study level and delivers assigned clinical study/studies per the Operational Execution Plan (OEP) and clinical study protocol
- Fosters an agile culture within assigned studies to achieve sprint goals and cycles, maximizing collaboration and minimizing dependencies in order to achieve long-term business impact
- In collaboration with regulatory writing and clinical development, promotes operational excellence in the development of global clinical study protocol(s), by translating the approved study concept sheet(s) into efficient, high quality, executable clinical protocols, and study-related documents
- Create effective CTT dynamics and achieve on performance, prioritization and communication in close collaboration with CTT sub-team leaders
- Proactive risk management and inspection readiness
- Fosters a close working relationship with SSO Clinical Project Managers (CPMs), VPG Vendor Program Managers (VPMs) and CDO Trial Data Scientist (TDS) to deliver on clinical study objectives and to strengthen the relationship between the global and local teams
- Oversees study recruitment and responsible for activating mitigation strategies in collaboration with the SSO Clinical Project Managers (CPMs)
- Ensures proper handling of all study close out activities including but not limited to site close out, final drug accountability and audit readiness of Trial Master File documentation
- Partners and collaborates with PSP/Clinical Operations Program Head (COPH) to deliver clinical studies

in alignment with program strategy
- Achieves excellence in study operations and management through process improvement in collaboration with the Study Leadership Community Lead/Host and GCO Process, Training, and Compliance (PTC)

**Essential requirements:**

- Bachelor's degree in life sciences/healthcare (or clinically relevant degree) is required. Advanced degree is preferred.
- ≥ 4 years of recent involvement in clinical research or drug development in an academic or industry environment spanning clinical activities in Phases I through IV
- ≥ 3 years of recent contribution to and accomplishment in all aspects of conducting clinical studies (e.g., planning, executing, reporting and publishing) in a global/matrix environment in pharmaceutical industry or a contract research organization, including expert knowledge of international standards (GCP/ICH), health authorities (FDA/EMA), local/National Health Authorities regulations and Novartis standards
- Experience in managing people globally in a complex matrix environment preferred
- Experience in developing effective working relationships with internal and external stakeholders
- Excellent communicator and presenter (oral and written); ability to communicate at all levels
- Strong negotiation and conflict resolution skills and enterprise mindset, demonstrated by ability to drive for aligned solutions for SSO and GCO/GDD
- Strong project management skills and demonstrated ability to meet timelines
- Superior strategic thinking with strong analytical and problem-solving skills
- Knowledge of appropriate therapeutic area preferred

**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

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División
Development
Business Unit

Innovative Medicines
Ubicación
Reino Unido
Sitio
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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