# Study Director (m/f/d)

Job ID
REQ-10048863

5月 01, 2025

Switzerland

## 摘要

Location: Basel, Switzerland

Role Purpose:
In Study Leadership we execute our trials in a community-driven and innovative way for faster quality delivery to patients. We are looking for a Study Director to join our global team in Basel.

The Study Director is independently accountable for the execution and delivery of the GCO supported clinical studies of medium to highly complexity and of high priority for Novartis, per the Operational Execution Plan (OEP) and clinical study protocol.
The Study Director co-leads together with the Clinical Science Lead (CSL) the cross-functional clinical trial team (CTT), guides planning and management of the assigned clinical study/studies end-to-end to achieve Global Program Team (GPT), Global Clinical Team (GCT), and GCO objectives.
Accountable for proactive, iterative operational planning with effective contingencies and embedded risk management mindset in CTT. Oversee budget and people allocation within assigned study/studies

## About the Role

**Major accountabilities:**

- Co-leads with the CSL the clinical trial team in collaboration with the Clinical Operations Program Head (COPH), delivery of multiple complex global studies and promotes learning, sharing, consistent performance, and operational excellence through an agile mindset, agile principles, and a team of team ' s model
- 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
- 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. Ensures systems are maintained with up-to-date study status, risks, and issues
- Responsible for developing clinical study timelines in collaboration with the Clinical Operations Program Head (COPH), and overseeing assigned study budgets
- Oversees study recruitment and responsible for activating mitigation strategies in collaboration with the SSO Clinical Program 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
- Promotes operational excellence and contributes to the development of Clinical Study Reports; reporting of clinical study results, and internal/external publications, when appropriate
- Achieves excellence in study operations and management through process improvement in collaboration with the Study Leadership Community Lead and GCO Process, Training, and Compliance (PTC)

**Essential Requirements:**

- Education: Bachelor ' s degree in life sciences/healthcare (or clinically relevant degree) is required. Advanced degree is strongly preferred.
- $\geq$ 7 years of recent involvement in clinical research or drug development in an academic or industry environment spanning clinical activities in Phases I through IV studies of medium to highly complexity
- $\geq$ 3-5 years of recent contribution to and accomplishment in all aspects of conducting clinical studies of medium to highly complexity and of high priority for Novartis (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
- Management of virtual teams. Proven ability and strong experience leading teams and building capabilities
- Experience in developing effective working relationships with internal and external stakeholders

- Excellent communicator and presenter (oral and written); ability to communicate at all levels
- Excellent negotiation and conflict resolution skills and enterprise mindset
- Strong project management skills and demonstrated ability to meet timeline
- Proven track record in study operations process improvement(s)

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.

Accessibility and accommodation
Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to inclusion.switzerland@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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

部门
Development

Business Unit
Innovative Medicines

地点
Switzerland

站点
Basel (City)

Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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