Study Start-up CRA -Hungary(home-based)

Job ID
REQ-10010299
Jul 15, 2024
Hungary

Summary

The Study Start-Up CRA is accountable for site selections as well as study-specific start-up activities and deliverables of assigned sites for Phase I-IV GDD trials within the country in adherence with monitoring procedures and processes in accordance with ICH/GCP, local regulations and SOPs. Proactive site preparation and early identification of real site needs and issues and close handover to execution CRA for all sites is key (from issue management to risk identification)

About the Role

Major accountabilities:

- Supports country SSU strategy in close collaboration with SSO Study Start-Up Team Lead, SSO Study Start-Up Manager, SSO Feasibility Manager as well as SSO Site Partnership Manager
- Accountable for timely start-up activities from country allocation until site greenlight at assigned sites
- Conducts site selection visits, verifies site eligibility for a specific study
- Main contact for trial sites during site selection, study start-up and IRB/IEC and HA submission preparation
- Ensures timelines, accuracy, and quality of country and site TMF documents in study start-up and make sure that time schedule for study start-up are met as planned
- Facilitates the preparation and collection of site and country level documents
- Collects submission relevant site-specific documents (e.g., FD, CV, GCP certificates, DSL...) for all relevant site personnel within agreed timelines
- Supports Study Start-Up Manager in preparation of country-specific documents and vendor set-up activities
- Supports preparation of financial contracts between Novartis and sites and investigators as needed and negotiates investigator payments as needed
- Supports preparation of audits and inspections as applicable
- Supports reduction of formal site-specific IRB/IEC deficiencies
- 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
- Ensures sites are prepared for “Green Light” and is accountable to send the Green Light to SSU Manager for review and approval

Minimum Requirements:
Work Experience:

- Minimum 3 years' experience in clinical operations in a monitoring / site management role
- Advanced understanding of all aspects of clinical drug development including strong knowledge of international standards (GCP/ICH), health authorities (FDA/EMA) and local/National Health Authorities regulations, with particular emphasis on trial set-up, execution, and monitoring
- Central/in-house monitoring or field monitoring experience is desirable

Skills:

- Strong site management capabilities with demonstrated negotiating and problem-solving skills
- Strong interpersonal and conflict resolutions skills
- Ability to travel, e.g., for site selections(up to 30% of working time)
- Ability to manage multiple priorities and manage time efficiently
- Good communication skills, ability to influence others & Relationship management
- Fluent Hungarian and English (written and spoken)

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

Division
Development
Business Unit
Innovative Medicines
Location
Hungary
Site
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-10010299

Study Start-up CRA -Hungary(home-based)

Apply to Job

Source URL: *https://www.adacap.com/careers/career-search/job/details/req-10010299-study-start-cra-hungary-home-based*

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://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Budapest/Study-Start-up-CRA--Hungary--home-based-_REQ-10010299
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Budapest/Study-Start-up-CRA--Hungary--home-based-_REQ-10010299