Associate, CRA at Novartis, japan

August 9, 2021 | News

Play a role in the global development of innovative drugs (antibody-drug, tumor immunotherapy, regenerative medicine, etc.).



Apply Now !

Your responsibilities include, but not limited to:

- Performs site selection for potential sites to evaluate their capabilities for conducting a clinical trial. Recommends sites to participate in clinical trial.
- Performs Site Initiation Visit, ensures site personnel is fully trained on all trial related aspects. Performs continuous training for amendments and new site personnel as required. Retrains site personnel as appropriate.
- Performs continuous monitoring activities (onsite and remote). Implements site management activities to ensure compliance with protocol, GCP, global and local regulations, global and local processes to secure data integrity and patient safety.
- Performs Site Closeout activities per SOPs and applicable regulations to ensure that site is aware of any follow up activity and archiving requirements.
- Collaborates with Clinical Study Manager and Medical Science Liaison to ensure recruitment plans and execute contingency plans, as needed.
- Play a role in the global development of innovative drugs (antibody drug, tumor immunotherapy, regenerative medicine, etc.).

What you'll bring to the role:

- Manage investigational sites and conduct appropriate clinical trials.
- Ensure and supports overall ICH-GCP/J-GCP conformity and compliance in clinical study.

- Delivering innovative drugs to patients as quickly as possible.

Minimum Requirements

Education:
Degree in scientific or healthcare discipline.

Languages:
Fluent English (Oral and spoken), Fluent in local language (Japanese)

Experience/Professional requirement:
Minimum of 3 to 5 years experiences in site monitoring
Competencies:

- Excellent knowledge of the drug development process specifically clinical trial/research
- Knowledge of international standards (GCP/ICH, FDA, EMEA)
- Ability to manage multiple priorities and manage time efficiently.
- Basic project management skills to support in CSM activities.

Skills & Knowledge:

- Ability to travel domestically (and possibly internationally) as needed to study sites and for training and meetings.
- A minimum of 50% overnight travel may be required.
- Advanced communication skills, ability to influence others.
- Good strategic thinking: Ability to anticipate potential issues and take appropriate actions with or without supervision.
- Advanced data accuracy: Ability to work focused with a great attention to detail.
- Ability to manage sites independently; Proven ability to work independently with or without minimal supervision by direct

You'll receive: (not mandatory)
Super Flex working time, Work from home system

Why consider Novartis?

817million. That's how many lives our products touch. And while we're proud of that fact, in this world of digital and technological transformation, we must also ask ourselves this: how can we continue to improve and extend even more people's lives?

Apply Now !