Randomization Office Specialist

Job ID
REQ-10031413
déc 03, 2024
Inde

Résumé

The Randomization Office Specialist is accountable to provide various Randomization office services including approval of randomization list, ensure the compliance of randomization process, verification and release of randomization/medication files working closely with GDD functions and other partner groups. Contribute and responsible for ensuring Randomization data accuracy and integrity, and keep the blinding status during the whole course of trials, all with minimal supervision.

About the Role

Accountabilities:

- Gate keep randomization codes ensuring the blinding status is maintained according to the trial protocol.
- Generates and reviews randomization schedules per the protocol and randomization specifications.
- Ensure all the randomization operations is compliance with randomization process. This encompasses randomization, blinding, IVRS usage, regulatory requirements, trial design elements, and current processes / SOP's.
- Perform regular randomization office activities: approval, review, qc, and release of randomization and medication files, assessment of planned/unplanned release requests.
- Is familiar with and stays current with the latest industry practices and updated regulatory guidelines.
- Represent function in cross-organizational and/or GCO initiatives
- Deputize as necessary for supervisor
- Optionally, support other service areas (e.g. Governance of GCO wide corrective actions and preventative actions, deviation management) , etc, as assigned

Activities & Interfaces:

Partner with Clinical Trial Teams to consult on randomization design elements and Global Clinical Supply (TRD) on the configuration of clinical packaging requests. This encompasses randomization, blinding, IVRS usage, regulatory requirements, trial design elements, and current processes / SOP's.

Key Performance Indicators

- State of the art and well controlled processes and practices driving efficiency/productivity, quality, and compliance – measured through KPIs/metrics/Survey feedback
- Timely and accurate maintenance of randomization file processing
- Demonstrated efficiency gains (e.g. reductions in time, cost, risk) to GDD through targeted process improvements in the randomization operations space
- Ensure that customer demands are identified, prioritized and align

Education:

- Bachelor’s degree or equivalent experience in engineering, mathematics, statistics, computer science, or health sciences/related field

Languages:

- Fluent English (oral and written)

Experience/Professional requirements:

1. At least 1-2 years relevant experience (or equivalent breadth of Pharmaceutical experience).

2. Good understanding of clinical development, quality and regulatory standards and policies relevant to Data Management, Statistical Reporting, Biostatistics, Medical Writing (e.g. GCP, ICH)

3. Strong influencing and negotiating skills and excellent problem solving skills.

4. Good knowledge of the design of randomized controlled clinical trials.

5. Successful experience working in cross-functional teams and management of projects

6. High degree of results-orientation and ability to execute

7. Must be able to organize, prioritize and work effectively in a constantly changing environment

8. Experience in driving initiatives and innovation

9. Strong communication and collaboration skills.

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

Division
Development
Business Unit
Innovative Medicines
Emplacement
Inde
Site
Hyderabad (Office)
Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Recherche & Développement

Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

Accessibility and accommodation

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

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Job ID
REQ-10031413

Randomization Office Specialist

Apply to Job

Source URL: *https://www.adacap.com/careers/career-search/job/details/req-10031413-randomization-office-specialist*

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/Randomization-Office-Specialist_REQ-10031413
5. mailto:diversityandincl.india@novartis.com
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/Randomization-Office-Specialist_REQ-10031413