

Randomization Office Specialist

Job ID
REQ-10031413
Dec 03, 2024
India

Summary

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.

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Division

Development

Business Unit

Innovative Medicines

Location

India

Site

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Research & Development

Job Type
Full time
Employment Type
Regular
Shift Work
No
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