



Function profile

GENERAL INFORMATION

Function: Senior Cluster Statistician
Reports to (function): Head of Cluster
Supervisory Statistician or Project Statistician
Department: GCRD / BCDM
Company: Novartis Vaccines & Diagnostics

JOB PURPOSE

The Senior Cluster Statistician assumes the role of an independent Statistician and is responsible for all statistical aspects of individual clinical trials within a vaccine cluster. He/she takes on project level tasks as required.

MAJOR ACCOUNTABILITIES

- Provides expert consultation and advice in quantitative/statistical, experimental design, and data management issues. Works with the clinical monitor and cluster team to develop clinical protocols, analysis plans and final study reports for clinical development projects. Plans, coordinates, and produces statistical analyses and summaries in support of product development.
- Member of core clinical cluster team, attend meetings as and coordinates activities for assigned clinical trials with internal data management and programming staff, medical writing and regulatory affairs.
- Ensure that clinical development projects meets scientific, regulatory, quality, and commercialization requirements
- Plan and track project level activities for B&SR.
- Support submission activities, like ISS, ISE, briefing books.
- Interact with Clinical Data Management as appropriate.
- Interact with Health Authorities and external consultants as appropriate. Support and defend analyses and their interpretation at Health Authority Meetings. Represent Biostatistics at FDA Advisory Committee meetings.
- Maintain records for all assigned projects and archive trial / project analysis and associated documentation.
- Coach and mentor cluster Statistician(s)

JOB DIMENSIONS

Number of associates: none

Financial responsibility: none

Impact on the organization:

- Timely preparation and delivery of high quality protocols and analyses for clinical study reports, to be included in regulatory submissions to Health Authorities
- Efficient production of analyses and reports of clinical trials
- Increased quality of decisions (early stopping of non promising projects and promotion of promising ones).

PERFORMANCE INDICATORS

- Quality and timeliness of statistical trial and project contributions as assessed by the Clinical Program Leader and/or Supervisory Statistician
- Adequate representation of Biostatistics in the Global Clinical Team, health authority meetings, and effectiveness of communication, as assessed by the Clinical Program Leader and/or Global Head Biostatistics.
- Quality and timelines of specifications to the programmers as assessed by feedback by the programming team

EDUCATION / EXPERIENCE

Desirable degrees:

Ph.D. in statistics, biostatistics or mathematics with at least 2 years directly related experience (pharmaceutical industry preferred), or Masters Degree. in statistics, biostatistics or related area with at least 4 years directly experience in pharmaceutical industry

Languages:

English, excellent spoken and written

Experience:

- Demonstrated sound knowledge of statistical applications.
- Awareness of appropriate regulations and guidance documents.
- Preferably SAS programming knowledge.
- Some Medical knowledge, especially in relation to specific vaccines area.
- Strong problem solving skills and sound statistical judgment. Technical capability to address common statistical problems arising in work.
- Attentiveness to detail.
- Strong interpersonal skills. Effective oral & written communication skills.
- Ability to effectively represent Biostatistics and Clinical Data Management in multidisciplinary meetings.
- Demonstrated ability to complete complex tasks on a timely basis with minimal supervision; well organized.
- Good project management skills.
- Good team player, good business ethics