Roles, Key Performance Expectations for CRE Biostatisticians I-IV

Biostatistician IV

**Role:** Biostatisticians ensure the integrity, validity, and accuracy of analyses and reporting of CRE's clinical data.

**Key Performance Expectations**

**Analysis plans are clear, detailed and appropriate**

* Recognizes and points out areas of concern in study documentation and proposes solutions regarding:
  1. Study design
  2. Sample size/power
  3. Data collection
  4. Proposed analysis approaches
* Reviews (or drafts) the study Statistical Analysis Plan and provides feedback
* Leads manuscript calls as needed to clarify aims and analyses and develops Manuscript Analysis Plans
* Develops mock tables, listings, and figures to plan the presentation of results

**Analysis datasets are appropriate and accurate for planned analyses**

* Reviews data collection forms for alignment with study aims
* Tests import of raw data extracts into statistical software
* Creates and maintains analysis datasets, dataset specifications, and programs in line with planned analyses
* Monitors raw and derived data by implementing a risk based statistical monitoring plan
* Works with clinical data managers to resolve data issues
* Completes all required analysis dataset quality control activities for each deliverable

**Results are high quality in all statistical output**

* Prepares results (tables, listings, and figures) as described in analysis plans and mock content
* Provides interpretations of results to investigators and study teams in study meetings, calls, or through email
* Reviews manuscript drafts for accuracy of statistical methods and interpretation of results
* Completes all necessary quality control activities based on deliverable risk level

Biostatistician III

**Role:** Biostatisticians ensure the integrity, validity, and accuracy of analyses and reporting of CRE's clinical data.

**Key Performance Expectations**

**Analysis plans are clear, detailed and appropriate**

* Recognizes and points out areas of concern in study documentation and identifies potential solutions regarding:
  1. Study design
  2. Sample size/power
  3. Data collection
  4. Proposed analysis approaches
* Reviews the study Statistical Analysis Plan and provides feedback
* Leads manuscript calls as needed to clarify aims and analyses and develops Manuscript Analysis Plans
* Develops mock tables, listings, and figures to plan the presentation of results

**Analysis datasets are appropriate and accurate for planned analyses**

* Reviews data collection forms for alignment with study aims
* Tests import of raw data extracts into statistical software
* Creates and maintains analysis datasets, dataset specifications, and programs
* Monitors raw and derived data by implementing a risk based statistical monitoring plan
* Works with clinical data managers to resolve data issues
* Completes all required analysis dataset quality control activities for each deliverable

**Results are high quality in all statistical output**

* Prepares results (tables, listings, and figures) as described in analysis plans and mock content
* Provides interpretations of results to investigators and study teams in study meetings, calls, or through email
* Reviews manuscript drafts for accuracy of statistical methods and interpretation of results
* Completes all necessary quality control activities based on deliverable risk level

Biostatistician II

**Role:** Biostatisticians ensure the integrity, validity, and accuracy of analyses and reporting of CRE's clinical data.

**Key Performance Expectations**

**Analysis plans are clear and detailed**

* Recognizes and points out potential areas of concern related to study design, statistical, or data issues and identifies potential solutions
* Reviews the study Statistical Analysis Plan and provides feedback
* Leads manuscript calls as needed to clarify aims and analyses and assists in developing Manuscript Analysis Plans
* Develops mock tables, listings, and figures to plan the presentation of results according to planned analyses

**Analysis datasets are appropriate and accurate for planned analyses**

* Reviews data collection forms for alignment with study aims
* Tests import of raw data extracts into statistical software
* Creates and maintains analysis datasets, dataset specifications, and programs
* Monitors raw and derived data based on a risk based statistical monitoring plan
* Works with clinical data managers to resolve data issues
* Completes all required analysis dataset quality control activities for each deliverable

**Results are high quality in all statistical output**

* Prepares results (tables, listings, and figures) as described in analysis plans and mock content
* Provides interpretations of results to investigators and study teams in study meetings, calls, or through email
* Reviews manuscript drafts for accuracy of statistical methods and interpretation of results
* Completes all necessary quality control activities based on deliverable risk level

**Demonstrates compliance to biostatistics working guidelines**

* Regularly reviews working guidelines
* Corrects deviations from working guidelines when they are found

Biostatistician I

**Role:** Biostatisticians ensure the integrity, validity, and accuracy of analyses and reporting of CRE's clinical data.

**Key Performance Expectations**

**Analysis plans are clear and detailed**

* Discusses concerns related to study design, statistical, or data issues with faculty or supervising statistician
* Reviews the study Statistical Analysis Plan and provides feedback
* Participates in manuscript calls and meetings to help clarify aims and analyses
* Develops mock tables, listings, and figures to plan the presentation of results according to planned analyses

**Analysis datasets are appropriate and accurate for planned analyses**

* Tests import of raw data extracts into statistical software
* Creates and maintains analysis datasets, dataset specifications, and programs
* Monitors raw and derived data based on a risk based statistical monitoring plan
* Works with clinical data managers to resolve data issues
* Completes all required analysis dataset quality control activities for each deliverable

**Results are high quality in all statistical output**

* Prepares results (tables, listings, and figures) as described in analysis plans and mock content
* Provides results to investigators and study teams in study meetings, calls, or through email
* Reviews manuscript drafts for accuracy of reported results
* Completes all necessary quality control activities based on deliverable risk level

**Demonstrates compliance to biostatistics working guidelines**

* Regularly reviews working guidelines
* Corrects deviations from working guidelines when they are found