Biostatistician

MAJOR DUTIES

Biostatistical Services (45%):

1. Provides Biostatistical assistance during planning/conduct/analysis and publication of results phases of assigned multi-center clinical trials/studies
   a. During planning phase:
      i. Provides assistance to the principal proponent (or principal investigator (PI)) to establish planning committees (following CSP guideline) for the assigned studies and to conduct pre-planning and planning meetings;
      ii. Assists the PI and other planning committee members to study the feasibility of conducting the proposed study within the VA by identifying available patient cohorts at different VA medical centers from VA care utilization databases;
      iii. Assists the PI and the planning committee to initiate the process of medical center selection for the assigned studies;
      iv. Performs sample size and power calculations for the assigned studies;
      v. Assists the PI and other planning committee members to identify and finalize the primary and secondary hypotheses for the assigned studies;
      vi. Assists the principal proponent and other planning committee members to identify and finalize the primary and secondary outcome measures and the instruments that will be used to collect the measures;
      vii. Writes up the statistical analysis section of the protocol;
      viii. Prepares a preliminary statistical analysis plan (or SAP) or a Biostatistical Research and Data Processing plan (or BRDP);
      ix. Assists the principal proponent to finalize the Cooperative Studies Scientific Evaluation Committee (CSSEC) submission package that includes a research protocol, a preliminary SAP (or BRDP), draft case report forms, a template of informed consent form;
      x. Assists the PI to prepare the responses for the CSSEC reviewer comments for assigned studies;
      xi. Accompanies the PI to face-to-face CSSEC review panel meetings to defend the assigned studies for funding;
   b. During study conduct phase:
      i. Collaborates with the statistical programmer to generate randomization lists and assists the Clinical Data Manager (CDM) to set up the automated randomization system for the assigned studies;
      ii. Collaborates with the chair’s office and the Project Manager (PM) to develop study operations manual for assigned studies;
      iii. Provides assistance to the PI to plan and conduct the kick-off meetings where the participating medical centers’ staff are introduced to the research protocol and data collection/submission procedures etc.;
      iv. Participates in recurring study conference calls for executing committee meetings and study coordinators’ meetings;
      v. Provides study updates to VA Central Office (VACO), center director and other concerned staff members;
      vi. Initiates data reviews to ensure data integrity;
vii. Collaborates with the statistical programmer and the CDM to resolve identified data integrity issues;

viii. Prepares recurring study reports for various stakeholders – chair’s office, Data Monitoring Committee (DMC), Central Institutional Review Board (cIRB), VACO etc.;

ix. Provides detailed instructions to the statistical programmer for generating required statistical tables for variety of reports as mentioned in item vi.;

x. Reviews the statistical programs, written by the assigned statistical programmer, which will be used to generate tables (as outlined in the SAP) and to create analytic datasets for interim analyses (as outlined in the protocol);

xi. Performs interim analyses for the assigned studies (if required by the protocol) in collaboration with the in-house statistical support staff;

xii. Presents the DMC report during DMC meetings (either via phone or face-to-face)

c. During Analysis and Publication of study results phase:

i. Reviews statistical programs, written by the assigned statistical programmer, which will be used to generate tables (as outlined in the SAP) and to create analytic datasets for final statistical analyses (as outlined in the protocol);

ii. Performs final statistical analyses, using the locked data set, as outlined in the research protocols for the assigned studies;

iii. Prepares final statistical report in collaboration with the statistical support staff at the coordinating center;

iv. Assists the PI to prepare and publish the primary manuscripts;

v. Assists the PI to prepare and publish all the planned secondary manuscripts;

vi. Assists other investigators to conduct secondary analyses;

Study Team Management (40%):

1. Provides leadership and manages the in-house study teams (that includes a project manager (PM), a statistical programmer, a clinical data manager (CDM) and 1 or 2 data associates or computer assistants) for assigned studies to ensure efficient and effective services in study administration, data management and statistical support;
   
a. Assists the PM to prepare budget scenarios during planning phase;

b. Assists the PM in study start-up activities, e.g., center activation for randomization, collection of required documentations (training certificates, COI statements, financial disclosures etc.);

c. Assist the PM and the chair’s office to deal with the R&D offices of the participating centers and also to deal with cIRB in regards to initial approval and continuing approval for the assigned studies;

d. Assists the PM to establish a DMC for assigned studies;

e. Assist the PM to organize the travels for study related meetings – Planning meetings; DMC meetings, Kick-off meetings, annual meetings etc.;

f. Assists the CDM to design data collection tools (CRFs), to prepare a data management plan, to establish data cleaning procedures;

g. Assists the PM and the Quality Assurance Nurse (QAN) to monitor the performance of the participating medical centers using an established risk-based monitoring approach;

h. Assist the PM in study close-out activities, e.g., center decommissioning, complete submission of data collection tools etc.;
2. Ensures the assigned CSP studies are conducted according to most updated rules and regulations and ethics requirements (e.g., VA CSP guideline, HIPAA, FDA, ICH, GCP etc.);
3. Assists the chair’s office (PI and the national study coordinator) and the PM to manage day-to-day study related issues that includes recruitment monitoring, monitoring of data collection and submission processes, staff turn overs at participating centers, staff training, issues with completion and submission of informed consent forms (ICFs) etc.;
4. Collaborates with the Quality Assurance section to ensure alignment with the CSP quality manual and the SOPs for providing administration/data management/statistical services to the assigned studies;

Other Services (15%):

1. Participates in Biostatistics subdomain activities, if assigned, to represent the coordinating center;
2. Provides biostatical help to other CSP coordinating centers, if assigned by the section supervisor or the center management;
3. Submits abstracts on Biostatistical work performed at the center to national/international conferences, e.g., Annual meetings of Society for Clinical Trials or Joint Statistical Meetings etc.;
4. Submits non-study manuscripts to peer-reviewed journals for publication;
5. Participates in other CSP-wide activities to provide subject-matter expertise as assigned;
6. Serves in the faculty of Department of Epidemiology and Public Health, School of Medicine, University of Maryland (optional);

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