
OFFICE OF BIOSTATISTICS

Statistical Policy Coordinating Committee

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PURPOSE

- The purpose of this MAPP is to describe (1) the Statistical Policy Coordinating Committee (SPCC), (2) the procedure used to designate its members, and (3) the procedure used to establish subcommittees and working groups.
 - The MAPP also describes the responsibilities of the subcommittees and working groups of the SPCC.
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BACKGROUND

- The SPCC provides statisticians working within CDER with a mechanism for identifying and resolving important statistical policy issues and establishing consistent statistical policy and procedures across the various biostatistical components within CDER. The SPCC also provides a mechanism for dealing with statistical reviewer issues.
 - The statistical staff of CDER are assigned to one of three divisions of biometrics or to the Quantitative Methods and Research Staff (QMR) within the Office of Biostatistics. The majority of the statistical staff are co-located within the 15 medical review
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Originator: Director, Office of Biostatistics
07/28/99

divisions in the Office of Review Management (ORM). During the review of INDs, NDAs, and ANDAs, statistical policy questions arise for which there may be no clear policy or precedent. Such statistical issues can relate to study design, statistical aspects of data handling, and the analyses of data. Occasionally, CDER may be challenged on its perceived statistical standard or on the manner with which statistical decisions are reached. Historically, the approach used to deal with statistical policy issues was to establish an ad hoc working group and charge this working group with the responsibility of sorting out the policy issue. Examples of such working groups are the Covariate Adjustment Working Group, the Interim Analysis Working Group, and the Meta-Analysis Working Group.

Other ad hoc working groups have been established under various authorities within CDER to produce documents with a statistical policy component. For example, the draft guidance for industry *on Submitting Documentation for the Stability of Human Drugs and Biologics* (June 1998) and the *E-9 Statistical Principles for Clinical Trials* (September 1998) were developed as part of the International Conference on Harmonisation (ICH). Until now, there has been no formal mechanism to coordinate, develop, or secure broad input on statistical policy issues from all of the biometric divisions within CDER. Consequently, this MAPP establishes the Statistical Policy Coordinating Committee to achieve the above objectives.

ORGANIZATION

- **SPCC**
 1. **Chair** - The Director of the Office of (OB).
 2. **Executive Secretary** - Appointed by the SPCC Chair.
 3. **Voting Members**- Permanent members of the SPCC shall include:
 - Director and Deputy Director of OB;
 - Associate Director for Clinical Biostatistics;
 - Associate Director for Non-Clinical Biostatistics;
 - Directors of the Biometrics Divisions I, II, and III; and
 - Director, Quantitative Methods and Research Staff.

The Chair will designate four rotating members (senior reviewers from Biometrics staff) each to serve a two-year term.

4. **Invitees** will normally include, as the topics require, the chairs of the four CDER standing coordinating committees:
 - The Medical Policy Coordinating Committee;
 - The Pharmacology and Toxicology Policy Coordinating Committee;
 - The Chemistry and Manufacturing Policy Coordinating Committee; and
 - The Biopharmaceutics Policy Coordinating Committee.
5. **Other Participants** - As the need arises and with the concurrence of the SPCC, directors of appropriate organizational units within CDER, from other FDA centers, and from other Federal agencies may be invited to specific meetings of the SPCC to facilitate cross-center and/or Agency interactions to obtain consensus on certain controversial issues.

- **Working Groups**

For the purpose of this MAPP, a working group is defined as a group of individuals assigned a specific task with a defined completion date.

1. **Chair** - The Chair of SPCC will select a chair for each working group. The chair of the working group will report to the chair of the SPCC on a regular basis.
2. **Membership** - The working group chair will select members of the working group taking into account expertise and other staff who might be affected or have a special interest in the subject matter.
3. Each working group should, in general, not exceed five members. Working group chairs will explain to the members the goals, procedures, and time available to carry out the activities of the working group.
4. Each chair will serve for the duration of the project.

- **Subcommittees**

For the purpose of this MAPP, a subcommittee is defined as a standing committee established to deal with a function or issue that requires continual re-assessment (e.g., research and publications policy, training opportunities, the core statistical curriculum for CDER Staff College).

1. **Chair** - The Chair of the SPCC will select a chair for each subcommittee. The subcommittee chair will select the members of the subcommittee, taking into account each individual's interest and willingness to serve.
 2. A subcommittee should comprise members from each of the operating units of the Office of Biostatistics.
 3. Subcommittee chairs are expected to report semiannually to the SPCC, or as-needed, on the activities of the subcommittee and any recommendations that have been made.
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RESPONSIBILITIES

- **SPCC**
 1. Develops, recommends, and establishes CDER statistical policies and procedures that pertain to design, analysis, and evaluation of industry studies and submissions in CDER. Goals will be to ensure a high quality of statistical work and to promote consistency across divisions.
 2. Reviews CDER policy statements, such as the various GRP documents, CDER MAPPs, Good Statistical Review Practices, and ICH documents that contain important statistical policy issues to ensure that these documents are consistent among themselves and with good statistical practices.
 3. Identifies critical emerging statistical issues and areas that lack appropriate statistical methodologies and/or designs.
 4. Reviews the Office of Biostatistics research and training programs.
 - **The Chair**
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1. Presides over SPCC meetings, establishes the agenda, and sets the priorities for the activities of the SPCC.
2. Appoints chairs for working groups and subcommittees.
3. Manages and coordinates the subcommittees.
4. Reports the recommendations and positions of the SPCC to the Director of CDER.
5. Announces the establishment of new statistical policies to the biostatistical staff, ORM, and CDER (e.g., need for statistical experts and consultants).
6. Submits draft policies and procedures with statistical content to CDER management for clearance, if necessary.

- **The Executive Secretary**

1. In consultation with the Chair, organizes meetings and identifies statistical issues to be brought before the SPCC for discussion.
2. Distributes meeting agendas and related documents.
3. Maintains files of committee activities.
4. Prepares and distributes minutes of SPCC meetings to all OB statistical reviewers within 2 weeks of a formal meeting of the SPCC.
5. Records the important comments relative to the matters being discussed.
6. Ensures the accuracy of SPCC documents.

- **Working Group Chair**

1. Serves as a source of advice and source of relevant information by obtaining the necessary input from those affected by the policy under consideration.

2. Helps to clarify policies and procedures identified by SPCC. Ensures that draft policies, procedures, and guidances in the working group area of responsibility are submitted to SPCC for review to obtain the input of all who may be affected by them prior to circulation for comments in the Center.
3. Responds, as needed, to questions from outside the Center. However, all requests to document statistical policy, regardless of origin, should come through the SPCC before a subcommittee initiates work.
4. Obtains input on statistical policy documents from the experts in the field and develops documents for submission to SPCC.
5. Obtains input from within and outside CDER, where appropriate, for issues with far-reaching implications. The SPCC will determine whether or not the proposed policies and procedures should go outside CDER for review and comment, but the responsibility for such solicitation belongs to the subcommittee originating the document.

- **Subcommittee Chair**

1. Schedules and conducts meetings to fulfill the subcommittee goals. To implement this responsibility, the subcommittee chair shall prepare an agenda and distribute it to the members in advance of each meeting.
2. Prepares brief minutes of each subcommittee meeting and distributes them to the members, statistical team leaders, division directors, and members of SPCC.
3. Ensures that copies of all records of meetings and other deliberations are placed in a file for that specific subcommittee to be maintained by the Executive Secretary for the SPCC.
4. Maintains a task list describing major tasks the committee is undertaking, projected milestones, and completion dates and the current status of each project.
5. Reports semiannually to the SPCC on the activities of the subcommittee. In preparation for each report, the chair should provide the SPCC with an updated task list, a summary of achievements since the last report to the SPCC, a

projection of activities for the next 6 months, and a list of issues in which SPCC input is needed.

- **Subcommittee and Working Group Members**
 1. Represent their division's views on issues considered by the subcommittees or working groups that pertain to their areas of responsibility.
 2. Communicate to their division management about the deliberations of the subcommittees.
 3. Regularly attend meetings of the subcommittees or working groups for which they are designated representatives. If a member cannot attend a meeting, an alternate should be designated to attend with the concurrence of the chair.
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PROCEDURES

- **Meetings** - Meetings of the SPCC are held monthly or as needed.
 - **Voting** - At least 75 percent of the voting members of the SPCC are needed to constitute a quorum. If unanimous agreement is not reached on an issue brought to the committee for a vote, areas of disagreement will be documented in the SPCC minutes.
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EFFECTIVE DATE

This MAPP is effective upon date of publication.