

PROGRAM DESCRIPTION

OFFICE OF TRANSLATIONAL SCIENCES

OFFICE OF BIOSTATISTICS

STATISTICAL POLICY COUNCIL

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PURPOSE

This MAPP describes the organization, membership, responsibilities, and procedures of the Statistical Policy Council (SPC) in the Office of Biostatistics (OB), Office of Translational Sciences (OTS), Center for Drug Evaluation and Research (CDER). The MAPP is being revised to rename the current “Statistical Policy Coordinating Committee” to the “Statistical Policy Council” and to otherwise update the Council’s organization and procedures.

The SPC will provide senior leadership to the Center on statistical policy development and dissemination, including:

- Attention to and management of essential cross-cutting statistical policy
- Advocacy for the consistent and transparent application of statistical policy throughout the Center
- Promotion and coordination of communication both internally and externally on statistical policy decisions made by the SPC

BACKGROUND

The SPC provides a senior level forum to establish statistical policy for CDER and oversee its application in both pre- and post-market review activities and related programs. Statistical reviewers in CDER are assigned to one of eight Divisions of

Biometrics within the Office of Biostatistics. During their review work, statistical issues may arise for which there is no established policy or procedure. Such statistical issues can relate to study design, study conduct, data handling, data analysis, and interpretation of study results. While some variation in the application of statistical methods across disease areas is expected and desired, the consistent application of sound statistical principles throughout CDER is essential to OB's mission and reflects the need for clarity and consistency of reviews articulated in the CDER Strategic Plan for 2013-2017.

CDER is occasionally challenged on its perceived statistical standards, on the manner with which statistical decisions are reached, or on variation in the acceptance of statistical methods across medical divisions. Having a committee to establish statistical policy and guide reviewers in the application of those policies addresses this need.

The SPC will meet on a regular basis to consider statistical policy issues that are complex or precedent setting and require input from senior management in the Office of Biostatistics. Although the issues discussed by the SPC may have been triggered by a specific statistical review, the policy established by the SPC will be applied to all reviews for which the policy is relevant.

For the purposes of the SPC, statistical policy generally concerns one or more of the following: Clinical study/trial design; statistical analysis planning and execution; analysis data quality and/or standards; interpretation of results to establish favorable benefit-risk; data/trial monitoring for safety and/or effectiveness; post-marketing safety assessments; qualification of biomarkers and clinical outcome assessments; and statistical support of non-clinical assessments, e.g., carcinogenicity, chemical, manufacturing, and control processes, etc.

To be considered by the SPC, a statistical policy issue typically would meet one or more of the following criteria:

- A novel trial/study design
- A novel approach to address a statistical methodological issue
- A statistical policy issue on which the Office of Biostatistics seems to have taken inconsistent positions over time or across therapeutic areas
- Strategies for implementation of a new statistical policy
- Strategies for effective communication of new or existing statistical policies

This MAPP describes the organization, membership, responsibilities, and procedures for the SPC in the Office of Biostatistics.

RESPONSIBILITIES

Office of Biostatistics Director:

1. Appoints the Chair of the SPC.

2. Consults with the Chair to appoint a Secretary.
3. Serves as a Permanent voting member of the SPC.
4. Selects up to four at-large members of the SPC.
5. Invites other subject matter experts to the SPC meetings depending on the item(s) under discussion.
6. Works with the SPC Chair to appoint chairs for standing subcommittees, if any, and working groups.

Office of Biostatistics Deputy Director, Associate Directors, Division Directors:

1. Serve as permanent voting members of the SPC.
2. Division Directors may appoint a member of each working group.

The Statistical Policy Council:

1. Develops, establishes, and recommends CDER statistical policies and procedures that pertain to study design and conduct, data handling, statistical analysis, and interpretation of study results. The goals of the SPC are (i) to ensure the conduct of high quality statistical reviews based on sound statistical methodologies and the best available statistical practice in evaluating studies and submissions in CDER and (ii) to promote consistency of statistical reviews across biometrics divisions and across medical divisions and offices within CDER.
2. Provides input to the development and review of CDER policy documents generated outside the Office of Biostatistics. These documents often raise important statistical policy issues or impact existing statistical policies and procedures. The SPC ensures that these documents are consistent and reflect good statistical practices.
3. Identifies critical, emerging statistical issues and areas that lack appropriate statistical methodologies and study designs.
4. Determines when a policy issue, identified by the SPC or proposed for SPC consideration by a reviewer, merits formation of a working group or subcommittee. When identified, develop a clear and concise charge to the working group or subcommittee. This includes outlining the issues to be addressed by the group, and identifying expected deliverables and an anticipated timeline.
5. Reviews and evaluates the deliverables of working groups or subcommittees in a timely fashion.
6. If a working group produces a policy document, determines if the document is recommended for approval and adoption as statistical policy for OB or disapproved; additionally, determines if the policy document should be proposed to be further developed as a CDER guidance document.
7. If a working group makes a recommendation about review practice in a form other than through development of a policy document, determines if the

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- recommendation is approved and adopted or disapproved. If approved and adopted, determines if a new SOP is needed or an existing SOP should be modified.
8. Develops dissemination and training plan for each policy decision or document approved and adopted by the SPC; determines the scope of such plans for training reviewers outside of the Office of Biostatistics.
 9. Reviews the OB research and statistical/regulatory training programs.
 10. Identifies the need for statistical experts and consultants to serve as CDER Advisory Committee members.

Working Groups:

1. Seek further clarification from the SPC, if needed, to ensure the charge is well understood by all working group members.
2. Identify the information and expertise needed to perform the charge of the working group and seek input and additional expertise, as needed, to carry out the charge.
3. Evaluate existing approaches to the statistical problem or review practice under consideration.
4. Determine if new statistical methodologies are needed. If so, oversee the development of those methodologies.
5. Develop and return to the SPC a recommendation or policy document to adequately and appropriately address the charge of the working group.

Subcommittees:

1. Ensure the charge is understood by all subcommittee members. If necessary, seek further clarification from the SPC.
2. Identify the information and expertise needed to perform the charge of the subcommittee. Seek input and additional expertise, as needed, to carry out the charge.
3. Carry out the work of the subcommittee. Periodically evaluate if the original charge is still appropriate or needs modification. Advise the SPC of any changes needed.
4. PROCEDURES

Statistical Policy Council:

1. SPC meetings will be held monthly, or as needed. The program support specialist supporting the Immediate Office schedules the meeting time and location.
2. Decisions will be established through deliberation among all parties attending an SPC meeting, reaching resolution through consensus, or through majority voting, if consensus is not reached.

SPC Chair:

1. Presides over SPC meetings, prepares meeting agendas, and sets the priorities for activities of the SPC.
2. Appoints chairs to any working groups and subcommittees that the SPC determines are needed.
3. Ensures policy recommendations and documents produced by working groups or subcommittees are reviewed, discussed, evaluated, and voted upon. Ensures decisions are taken and can be acted on in a timely fashion following completion of the working group's or subcommittee's charge.
4. Ensures the dissemination and training plans developed by the SPC for new, or changes in existing, policies and procedures are carried out.
5. Provides periodic reports to the Director, Office of Biostatistics on the recommendations, actions, and positions taken by the SPC.
6. Presents new policy decisions and leads discussions about the implications of statistical policy changes to CDER's Medical Policy Council (MPC).

SPC Secretary:

1. Prepares minutes that record all decisions and actions taken by the SPC.
2. Distributes minutes at the start of each SPC meeting.
3. Maintains records documenting SPC decisions and actions. Provides access to those records upon request.

Working Group and Subcommittee Chairs:

1. Schedule and preside over working group and subcommittee meetings. Prepare agendas and minutes of the meetings.
2. Provide periodic reports to the SPC on progress of the working group or subcommittee. Include documentation of any activities undertaken during the reporting period, and challenges or issues encountered.

REFERENCES

1. FDA Center for Drug Evaluation and Research (CDER) Strategic Plan 2013-2017. Food and Drug Administration website.
<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/default.htm>. Updated November 25, 2013.

DEFINITIONS

Working Group: a group of individuals assigned a specific task with a defined deliverable and completion date.

Subcommittee: a standing committee established to address a policy issue that requires continual assessment or serve an on-going policy-related function for the Office. Examples include a Publications Subcommittee and a Reviewer Training Subcommittee.

AUTHORITY

The SPC will have the following authority:

- Establish statistical policy
 - Establish subcommittees
 - Establish working groups
 - Provide direction and feedback to subcommittees and working groups
 - Ratify subcommittee and working group recommendations
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ORGANIZATION

SPC

1. Chair: The Director of the Office of Biostatistics will appoint the Chair.
2. Secretary: The Office Director in consultation with the SPC Chair will appoint a Secretary.
3. Members: Permanent voting members of the SPC will include:
 - a. Director of the Office of Biostatistics
 - b. Deputy Director of the Office
 - c. Associate Directors of the Office
 - d. Division Directors within the Office
 - e. At-large members: the Office Director may select up to four at-large members to serve on a rotating basis.
4. Other Attendees: Deputy Division Directors are expected to attend SPC meetings but are non-voting.
5. Other Invitees: The Office Director and/or Chair may invite others to attend one or more meetings of the SPC, if the discussion of a particular topic will be enhanced by input from those experts.

Working Groups

1. Chair: The SPC Chair in consultation with the Office Director will select a chair for each working group.
2. Members: The Director of each Division of Biometrics (I – VIII) will have the opportunity to appoint a member of each working group but may decline. Topics for which the SPC determines that office-wide input is important will be required to have representation from all divisions. The Office Director may appoint a working group member from among the Deputy Director and Associate Directors

in the Immediate Office. The working group chair may select additional members of the working group, taking into account their expertise and interest in the topic. In general, working group membership should not exceed 8-10 members plus the chair.

Subcommittees

1. Chair: The SPC Chair in consultation with the Office Director will select a chair for each subcommittee.
2. Members: Subcommittees are required to have representation from each biometrics division. The Division Directors will appoint a member from their respective division to serve on the subcommittee. The Office Director may appoint a working group member from among the Deputy Director and Associate Directors in the Immediate Office.
3. Duration of service: Subcommittee appointments are for two-year terms, with the potential for re-appointment.

SUMMARY OF CHANGES

The Statistical Policy Coordinating Committee was established in 1999. The SPC is the new name for this committee. This MAPP provides an update to the original MAPP to better reflect current working practice and to facilitate timely decision-making regarding statistical policies and procedures.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
7/22/99	Initial	n/a
3/9/16	1	Committee renamed. MAPP updated to reflect current working practices.