

SMG 1256.2

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

OFFICE OF SURVEILLANCE AND BIOMETRICS

DIVISION OF BIostatISTICS

Effective Date: January 7, 2015

1. DIVISION OF BIostatISTICS (DKKWHA).

- A. Reviews critical materials submitted to or generated by Center including Investigational Device Exemptions (IDE), Premarket Approval Applications (PMA), 510K applications, standards and guidelines for statistical validity and consistency.
- B. Conducts original statistical research and modeling studies and collaborates in the design, analysis, and interpretation of laboratory and epidemiologic studies on the health effects of medical device use and exposure to radiation.
- C. Provides comprehensive statistical computational support to internal and external Center activities including collaborative design, analysis, and participation in the standards and compliance activities.
- D. Performs risk assessments and risk/benefit analyses for medical devices and radiation programs and participates with other Center components in regulatory and educational activities.
- E. Collaborates with statisticians in other Centers and Agencies on matters of mutual interest including methodological issues and statistical research.
- F. Interacts with national, international, public and private organizations to identify common statistical problems and areas of mutual interest associated with the regulation of medical devices and radiation.

2. THERAPEUTIC STATISTICS BRANCH I (DKKWHA1).

- A. Engages in all Division of Biostatistics activities in the area of vascular surgery, circulatory support, structural heart, peripheral vascular and interventional cardiology devices.
- B. Reviews critical materials submitted to or generated by Center including IDE, PMA, 510K applications, standards and guidelines for statistical validity and consistency.
- C. Conducts original statistical research and modeling studies and collaborates in the design, analysis, and interpretation of laboratory and epidemiologic studies on the health effects of medical device use.
- D. Provides comprehensive statistical computational support to internal and external Center activities including collaborative design, analysis, and participation in the standards and compliance activities.
- E. Performs risk assessments and risk/benefit analyses for medical devices and participates with other Center components in regulatory, and educational activities.
- F. Collaborates with statisticians in other Centers and Agencies on matters of mutual interest including methodological issues and statistical research.
- G. Interacts with national, international, public and private organizations to identify common statistical problems and areas of mutual interest associated with the regulation of medical devices.

3. THERAPEUTIC STATISTICS BRANCH II (DKKWHA3).

- A. Engages in all Division of Biostatistics activities in the area of orthopedic, surgical, dental, and neurological devices.
- B. Reviews critical materials submitted to or generated by Center including IDE, PMA, 510K applications, standards and guidelines for statistical validity and consistency.
- C. Conducts original statistical research and modeling studies and collaborates in the design, analysis, and interpretation of laboratory and epidemiologic studies on the health effects of medical device use.
- D. Provides comprehensive statistical computational support to internal and external Center activities including collaborative design, analysis, and participation in the standards and compliance activities.

- E. Performs risk assessments and risk/benefit analyses for medical devices and participates with other Center components in regulatory, and educational activities.
- F. Collaborates with statisticians in other Centers and Agencies on matters of mutual interest including methodological issues and statistical research.
- G. Interacts with national, international, public and private organizations to identify common statistical problems and areas of mutual interest associated with the regulation of medical devices.

4. THERAPEUTIC STATISTICS BRANCH III (DKKWHA4).

- A. Engages in all Division of Biostatistics activities in the area of orthopedic, surgical, dental, and neurological devices.
- B. Reviews critical materials submitted to or generated by Center including IDE, PMA, 510K applications, standards and guidelines for statistical validity and consistency.
- C. Conducts original statistical research and modeling studies and collaborates in the design, analysis, and interpretation of laboratory and epidemiologic studies on the health effects of medical device use.
- D. Provides comprehensive statistical computational support to internal and external Center activities including collaborative design, analysis, and participation in the standards and compliance activities.
- E. Performs risk assessments and risk/benefit analyses for medical devices and participates with other Center components in regulatory, and educational activities.
- F. Collaborates with statisticians in other Centers and Agencies on matters of mutual interest including methodological issues and statistical research.
- G. Interacts with national, international, public and private organizations to identify common statistical problems and areas of mutual interest associated with the regulation of medical devices.

5. DIAGNOSTIC STATISTICS BRANCH I (DKKWHA2).

- A. Engages in all division of Biostatistics activities in the area of in vivo diagnostic devices in all areas of medicine.

- B. Reviews critical materials submitted to or generated by Center including IDE, PMA, 510K applications, standards and guidelines for statistical validity and consistency.
- C. Conducts original statistical research and modeling studies and collaborates in the design, analysis, and interpretation of laboratory and epidemiologic studies on the health effects of medical device use.
- D. Provides comprehensive statistical computational support to internal and external Center activities including collaborative design, analysis, and participation in the standards and compliance activities.
- E. Performs risk assessments and risk/benefit analyses for medical devices and participates with other Center components in regulatory, and educational activities.
- F. Collaborates with statisticians in other Centers and Agencies on matters of mutual interest including methodological issues and statistical research.
- G. Interacts with national, international, public and private organizations to identify common statistical problems and areas of mutual interest associated with the regulation of medical devices.

6. DIAGNOSTIC STATISTICS BRANCH II (DKKWHA5).

- A. Engages in all Division of Biostatistics activities in the area of therapeutic and diagnostic radiological products and in vitro diagnostic devices in all areas of medicine.
- B. Reviews critical materials submitted to or generated by Center including IDE, PMA, 510K applications, standards and guidelines for statistical validity and consistency.
- C. Conducts original statistical research and modeling studies and collaborates in the design, analysis, and interpretation of laboratory and epidemiologic studies on the health effects of medical device use.
- D. Provides comprehensive statistical computational support to internal and external Center activities including collaborative design, analysis, and participation in the standards and compliance activities.
- E. Performs risk assessments and risk/benefit analyses for medical devices and participates with other Center components in regulatory, and educational activities.

- F. Collaborates with statisticians in other Centers and Agencies on matters of mutual interest including methodological issues and statistical research.
- G. Interacts with national, international, public and private organizations to identify common statistical problems and areas of mutual interest associated with the regulation of medical devices.

7. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Director, Center for Devices and Radiological Health and effective on January 7, 2015.

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OFFICE OF MEDICAL PRODUCTS AND TOBACCO
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OFFICE OF THE DIRECTOR

Therapeutic Statistics Branch I
Therapeutic Statistics Branch II
Therapeutic Statistics Branch III
Diagnostic Statistics Branch I
Diagnostic Statistics Branch II

STAFF MANUAL GUIDE 1256.2
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: January 7, 2015

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Devices and Radiological Health, Office of Surveillance and Biometrics, Division of Biostatistics organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Therapeutic Statistics Branch I
- Therapeutic Statistics Branch II
- Therapeutic Statistics Branch III
- Diagnostic Statistics Branch I
- Diagnostic Statistics Branch II