

**FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND  
FUNCTIONS**

**FOOD AND DRUG ADMINISTRATION**

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**OFFICE OF TRANSLATIONAL SCIENCE**

**OFFICE OF CLINICAL PHARMACOLOGY**

**DIVISION OF PHARMACOMETRICS**

Effective Date: 12/22/2008

**1. DIVISION OF PHARMACOMETRICS (DBNGCF).**

- A. In collaboration with the Office of New Drugs and other appropriate disciplines, coordinates and reviews opportunities for critical juncture meetings (e.g., EOP2A) with industry in order to optimize drug development. Participates fully in the regulatory process by providing important contributions to all industry meetings - from pre-IND to phase 4, including review of promotional materials and post-marketing safety that takes place in CDER.
- B. To improve the public health by increasing the efficiency and quality of clinical drug development with the application of model-based drug development. To develop quantitative model based tools to improve key drug development decisions (e.g., trial strategy and design, regulatory drug and label approval). Review INDs and NDAs containing clinical pharmacology modeling and simulation data submitted to the OND clinical Divisions and consulted to OCPB Divisions. To work collaboratively across therapeutic areas and disciplines to accomplish this mission. Create disease models predicting patient outcome that can be shared inside and outside the FDA and establishing a disease data library that can be used inside and outside FDA to promote understanding the disease process and how to measure improvement or worsening.
- C. Evaluates for the areas of pharmacokinetics, pharmacodynamics, pharmacometrics (e.g., dose response, population pharmacokinetics, modeling and simulation), drug metabolism and drug interactions (including drug-drug, drug-botanical, drug-food) analysis of exposure-QT prolongation, pharmacogenetics, bioavailability, bioequivalence, biopharmaceutics classification system, in vitro dissolution, in vitro-in vivo

correlation protocols and data submitted in support of Investigational New Drug Applications (INDs), New Drug Applications (NDAs), Biologic Licensing Agreements (BLAs), and their supplements and amendments. Recommends approval, disapproval, or amendments to new studies and/or protocols in these areas for all assigned drugs.

- D. Establishes recommendations or policy to define acceptable drug product performance and dosing regimens and establishes guidance for special population studies, bioavailability and other related biopharmaceutical studies. Sets policy for good review practices in clinical pharmacology and biopharmaceutics. Serves as a consultant to other Centers of the FDA, such as CDRH, in the review of combination products.
- E. Evaluates polymorphic metabolism data from clinical pharmacology studies, which may lead to modified clinical trial design (dosing) and also final labeling recommendations, particularly as it relates to pharmacogenetic factors.
- F. Provides educational opportunities and advises other CDER scientists and clinicians on topics related to clinical pharmacology and biopharmaceutics pertinent to other disciplines.
- G. Organizes and provides significant scientific input into FDA Advisory Committee meetings.
- H. Designs, initiates and monitors various internal and external regulatory science research projects and communicates important findings at national and international meetings as well as publications in peer-reviewed journals.
- I. Participates in the development of guidance and regulatory policy in scientific and regulatory areas characterized by new and emerging research, such as exposure response relationships, pharmacogenomics, drug-drug interactions, and other new technologies and sciences.

**2. AUTHORITY AND EFFECTIVE DATE.**

The functional statements for this Division were approved by the Director, Center for Drug Evaluation and Research on December 22, 2008.

<b>STATUS (I, R, C)</b>	<b>DATE APPROVED</b>	<b>LOCATION OF CHANGE HISTORY</b>	<b>CONTACT</b>	<b>APPROVING OFFICIAL</b>
Initial	12/22/2008	N/a	OC/OO/OM/OMP	Director, Center for Drug Evaluation and Research

**FOOD AND DRUG ADMINISTRATION  
OFFICE OF MEDICAL PRODUCTS AND TOBACCO  
CENTER FOR DRUG EVALUATION AND RESEARCH  
OFFICE OF TRANSLATIONAL SCIENCES  
OFFICE OF CLINICAL PHARMACOLOGY  
DIVISION OF PHARMACOMETRICS**



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The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Translational Sciences, Office of Clinical Pharmacology, Division of Pharmacometrics depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR