U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION & RESEARCH
OFFICE OF CLINICAL PHARMACOLOGY

Overview of Clinical Pharmacology Guidances: Providing Recommendations on Quantitative Approaches Used in Drug Development and Regulatory Assessment

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Division Director
Division of Pharmacometrics,
FDA/CDER/OTS/OCP

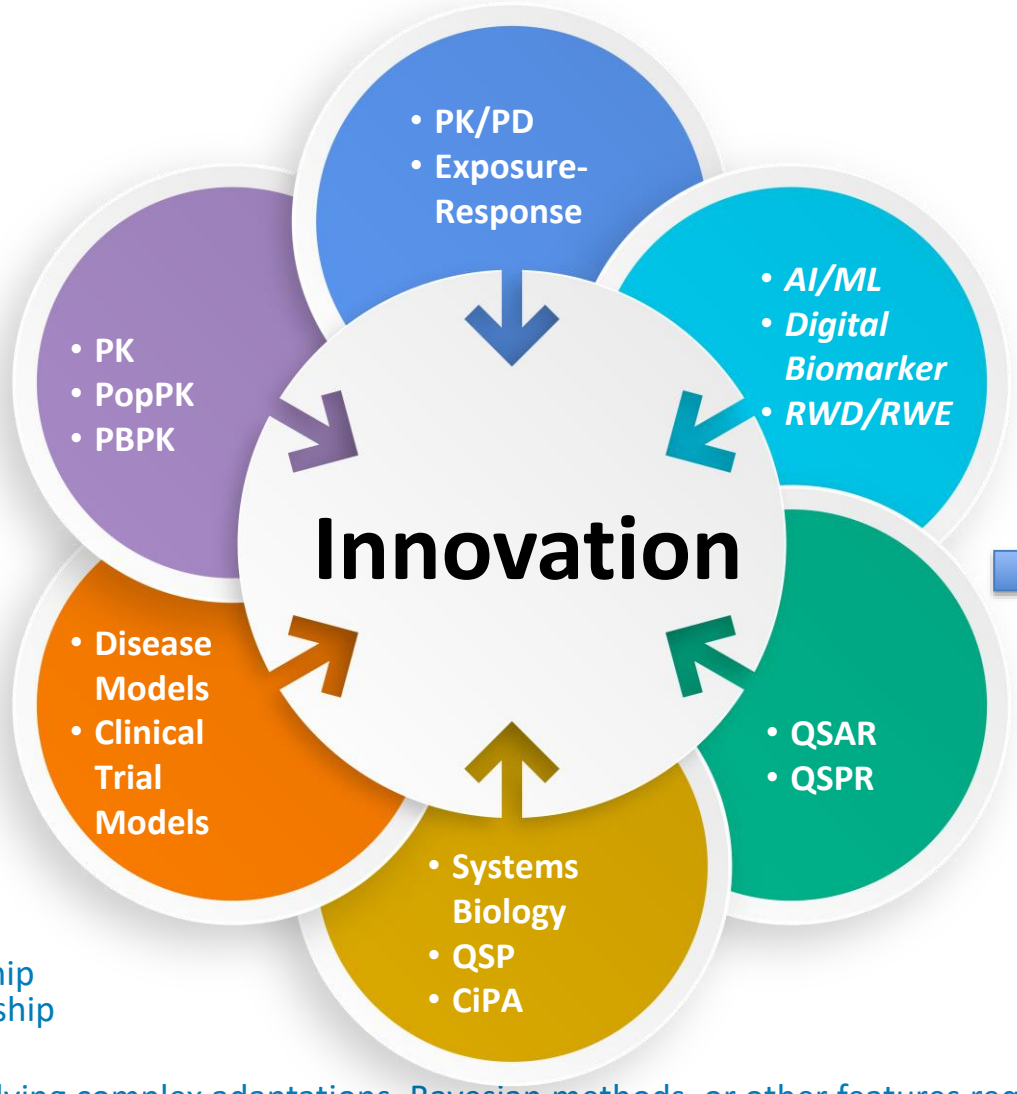
FDA-CERSI Public Workshop
(May 2024)

Outline

- Application of Quantitative Clinical Pharmacology to Promote Innovation.
  - Tools, Applications, Drivers for Quantitative Clinical pharmacology
  - Collaboration and Platform for Innovation
- Quantitative Clinical Pharmacology Associated Guidance
  - MIDD Overarching Guidance
  - Guidance for Specific Methodology
  - Application in Clinical Pharmacology
  - Application in Clinical Development
- Take-Home Message

Tools for MIDD

Development and application of exposure-based, biological, and pharmacological models derived from preclinical and clinical data sources to address drug development or regulatory issues*



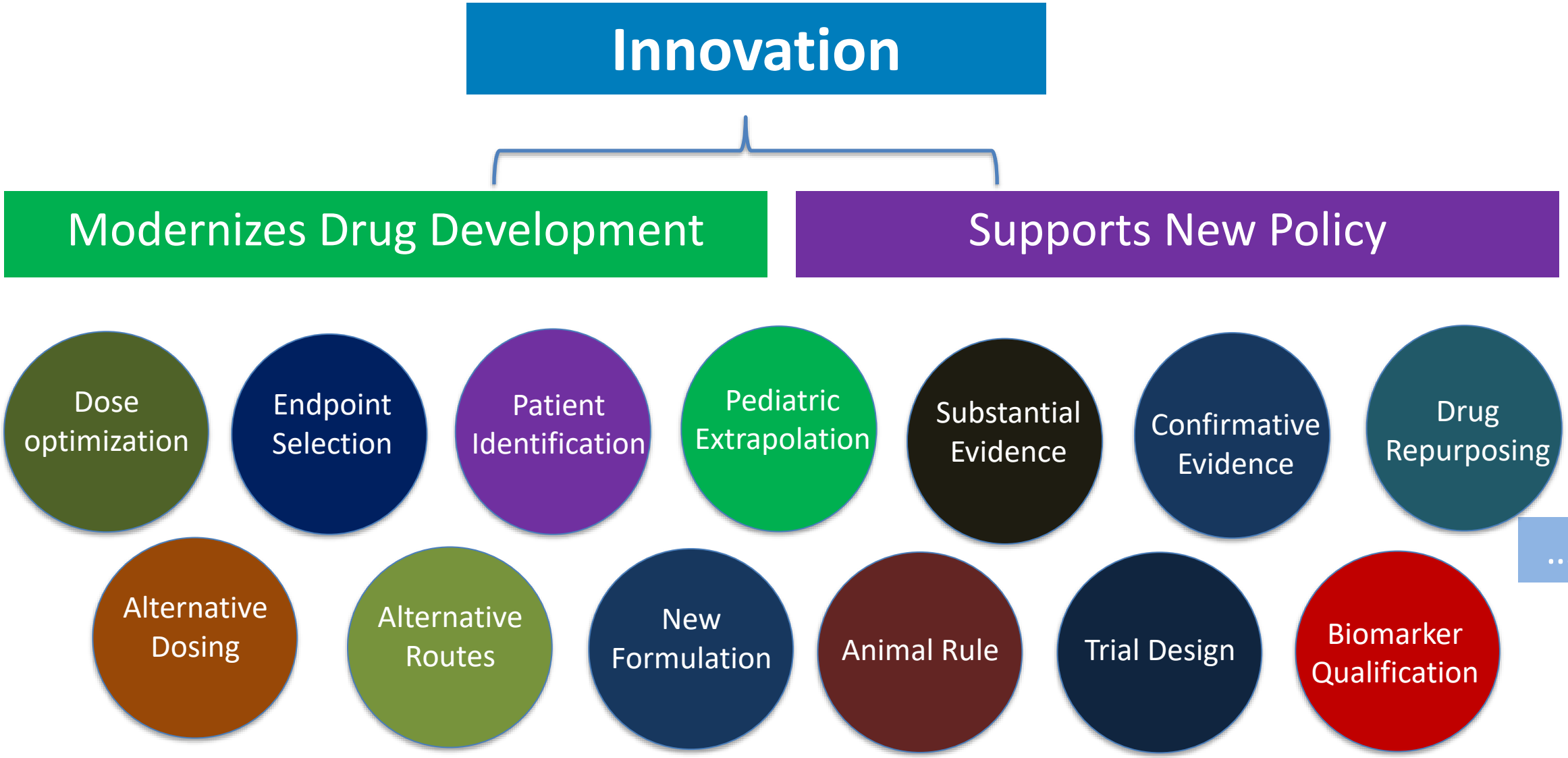
- **Modernize New Drug Development and Patient Care.**
- **Reshape Policy Development**

QSAR: Quantitative structure–activity relationship
QSPR: Quantitative structure–property relationship

* From PDUFA 6; Excludes statistical designs involving complex adaptations, Bayesian methods, or other features requiring computer simulations to determine the operating characteristics of a confirmatory clinical trial.

Huang SM 2019 AAPS

Application of Quantitative Clinical Pharmacology



Drivers for Quantitative Clinical Pharmacology

Focus: Innovation

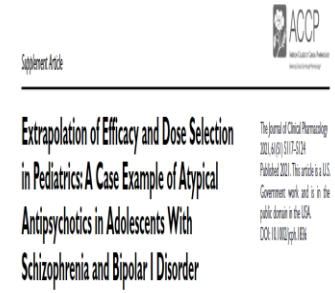
Policy Development	New policy and guidance based on experience accumulated through reviews and researches.
Sponsor Engagement	MIDD Paired Meeting Program and FFP Program for early interaction with the sponsor.
Broadened Collaboration	Collaboration through different disciplines at the FDA, and academia, industry, and other regulatory bodies.
Technical Exploration	Actively investing novel technologies. E.g., (digital) Biomarkers, Disease Modeling, AI/ML, QSP, RWE/RWD

Quantitative Clinical Pharmacology

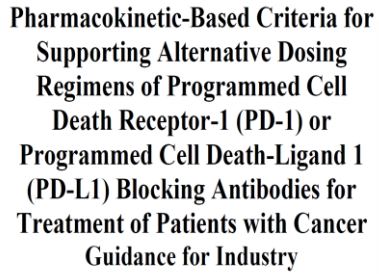
Skilled Review Staff and Leadership

Collaborations for Innovation

• Internal Collaboration



Joint research among OND, OCP, and OB to establish pediatric extrapolation, identify novel endpoints, select patients, etc

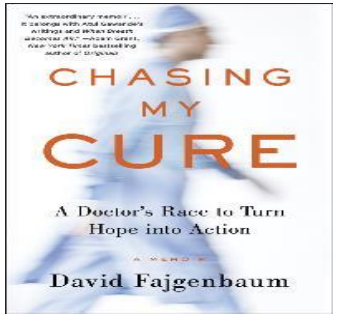


To establish new policy and guidance to streamline new drug development.

To engage internal stake holders for experience sharing, issue identification and technical discussion

• External Collaboration

Collaboration with Dr. Fajgenbaum at University of Pennsylvania to explore potential biomarkers for Castleman's disease



To achieve global harmonization on Model Informed Drug Development (ICH M15 MIDD guideline)

To establish technical standard.
To enhance experience sharing
To engage broad discussion on issues

ISoP
INTERNATIONAL SOCIETY OF PHARMACOMETRICS

Platform for Innovation

• MIDD Paired Meeting Program

Jointly administered by CDER and CBER for IND, NDA, and BLA holders to support the use of innovative modeling tools in a specific development program.

1. **Creating an environment that increases stakeholder acceptance of MIDD approaches**
2. **Developing standards and best practices that lead to consistent application and evaluation**
3. **Increasing capacity and expertise to address growing demands and innovation**

*: Model-Informed Drug Development Paired Meeting Program | FDA

• FFP Program

The Fit-for-Purpose (FFP) Initiative provides a pathway for regulatory acceptance of dynamic tools for use in drug development programs. It represents a joint effort between OCP and OB.

Disease	Tool	Trial
Alzheimer's Disease	Placebo/ disease progression	Trial Design
Multiple	MCP-Mod	Dose-finding
Multiple	Bayesian Optimal Interval (BOIN) design	Dose-finding
Multiple	Empirically Based Bayesian Emax Models	Dose-finding

*: Drug Development Tools: Fit-for-Purpose Initiative | FDA

Quantitative Medicine Center of Excellence

(Strategic Planning, Training, Outreach, Policy)

Broader

Deeper

Development Programs

Streamlines new drug development so that an effective treatment may reach patients sooner

Capability

Enhances our capability to promote the use of quantitative tools to streamline drug development

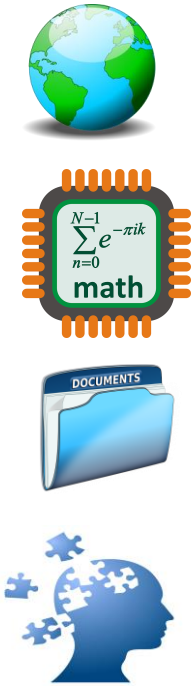
Synergized Effort

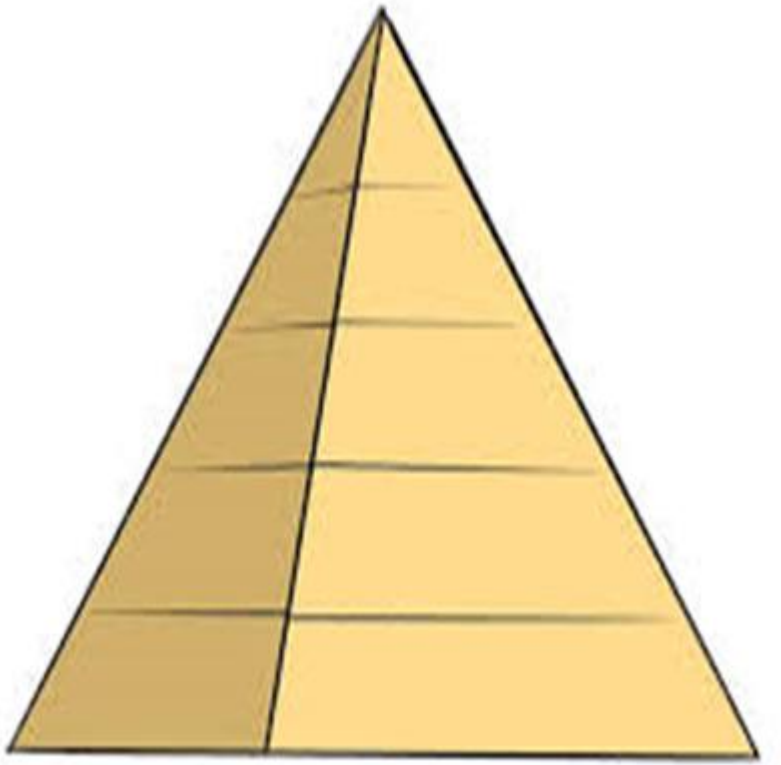
Provides opportunities for collaborations with internal and external stake holders.

Structure of Guidance (Quantitative Clinical Pharmacology)

Quantitative Clinical Pharmacology Related Guidance Structure

Overarching Guidance	ICH M15: .MIDD General Principles Guideline
Modeling Guidance	Population PK, Exposure-Response, PBPK Format and Content Guidance
Clin Pharm Guidance	DDI (In vitro), DDI (In vivo), Renal, hepatic impairment, ADC, Oligonucleotides, ……
Clinical Guidance	Pediatric extrapolation for partial onset seizure, hypertension, HIV-1 treatment, …





MIDD Overarching Guidance

ICH harmonisation for better health

Final Concept Paper

M15: Model-Informed Drug Development General Principles Guideline

2 November 2022

Endorsed by the Management Committee on 10 November 2022

Type of Harmonisation Action Proposed

A new, overarching guideline on General Principles for Model-Informed Drug Development (MIDD) to broadly cover general principles and good practices for use of MIDD in regulatory submissions.

Type of Action:

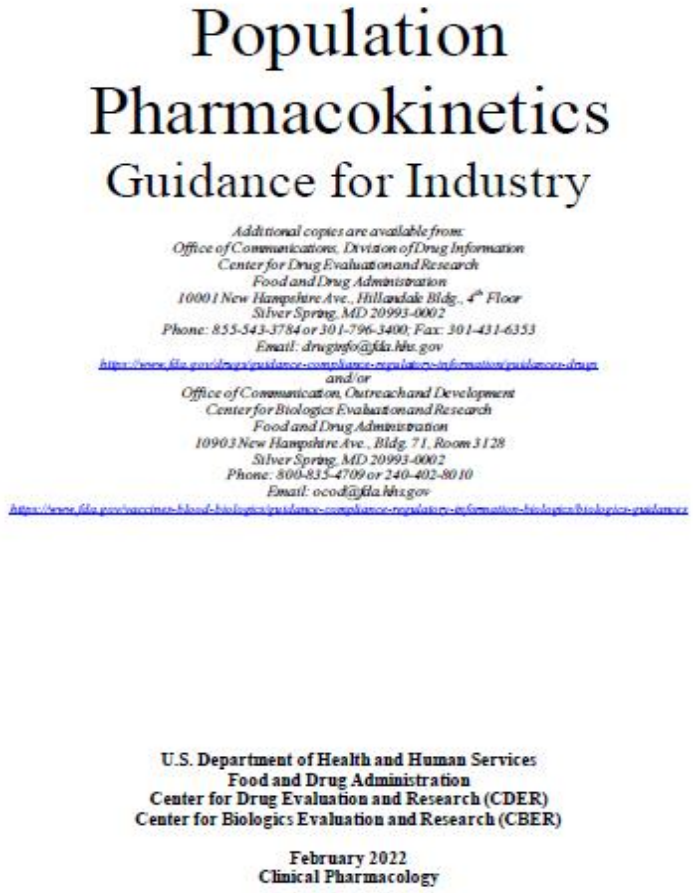
A new, overarching guideline broadly covers general principles and good practices for use of MIDD in regulatory submissions.

Topics

- Outline general scope and principles with respect to MIDD,
- Guidance on quantitative strategies, analysis and interpretation of results, standardization of reporting and documentation;
- Introduce the concept of a risk-based assessment,
- A framework for multidisciplinary interaction and dialogue;
- High-level recommendations with respect to interactions between sponsor and regulator.

Ref: M15: Model-Informed Drug Development General Principles Guideline. (Concept Paper)

Modeling: Population Pharmacokientics Guidance



Population Pharmacokinetics

Guidance for Industry

Additional copies are available from:
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Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov
https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs
and/or
Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 71, Room 3128
Silver Spring, MD 20993-0002
Phone: 800-835-4709 or 240-402-8010
Email: ocod@fda.hhs.gov
https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

February 2022
Clinical Pharmacology

Pop-PK:

Population PK analysis is a well-established, quantitative method that can explain some of the variability in drug concentrations among individuals .

Topics

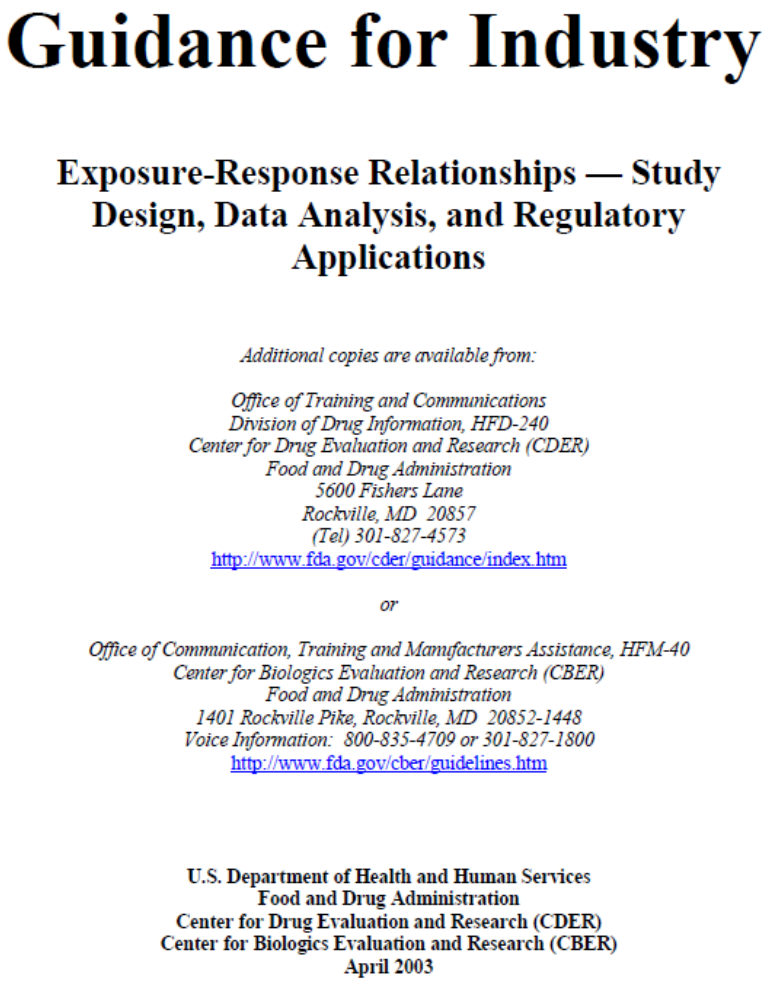
- Introduction
- Background
- Application of Pop-PK Analysis
- Data Used for Pop-PK Analysis
- Data Analysis
- Labeling Based On Pop-PK Analysis
- Pop-PK Study Reporting

History

Original (1999) → Draft (2019) → Final (2022)

Ref: Population Pharmacokinetics Guidance for Industry <https://www.fda.gov/media/128793/download>

Modeling: Exposure-Response Guidance



Guidance for Industry

Exposure-Response Relationships — Study Design, Data Analysis, and Regulatory Applications

Additional copies are available from:

Office of Training and Communications
Division of Drug Information, HFD-240
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
(Tel) 301-827-4573
http://www.fda.gov/cder/guidance/index.htm

or

Office of Communication, Training and Manufacturers Assistance, HFM-40
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration
1401 Rockville Pike, Rockville, MD 20852-1448
Voice Information: 800-835-4709 or 301-827-1800
http://www.fda.gov/cber/guidelines.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
April 2003

Exposure-Response Relationship:

exposure to refer to dose (drug input to the body) and various measures of acute or integrated drug concentrations in plasma and other biological fluid (e.g., Cmax, Cmin, Css, AUC).

response refers to a direct measure of the pharmacologic effect of the drug. (endpoints, biomarkers, surrogate, clinical effects)

Topics

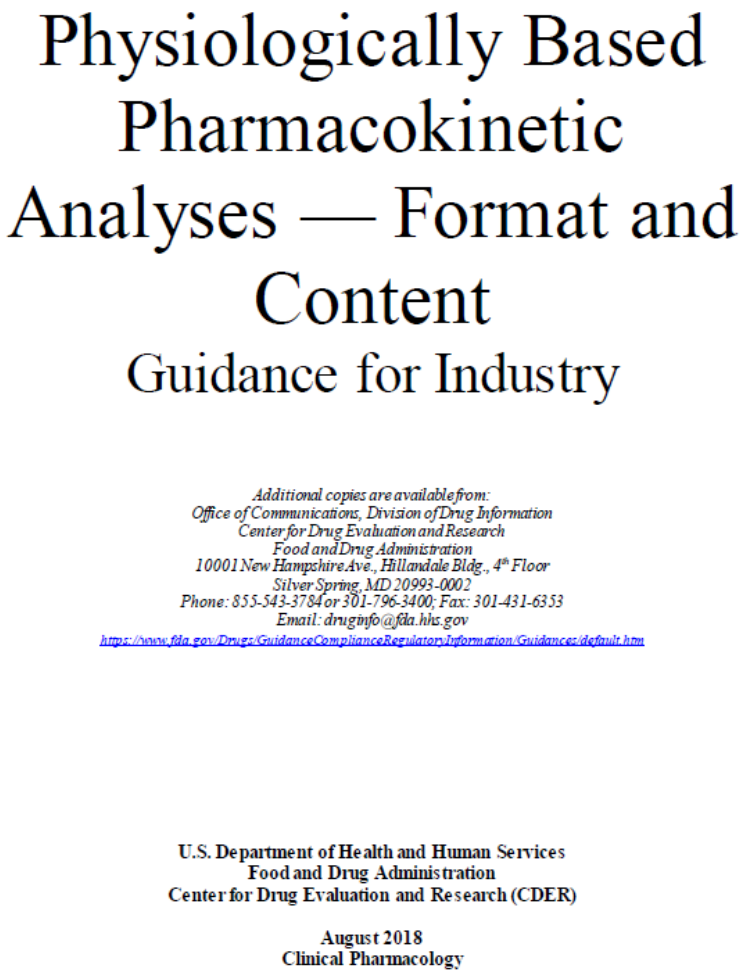
- Introduction
- Background
- Dose-Concentration-Response Relationships and Effects Over Time
- Designs of Exposure-Response Studies
- Modeling of Exposure-Response Relationships
- Submission Information: Exposure-Response Study Report

History

Original (2003) → Revision (Inclusive for Novel approaches)

Ref: Exposure-Response Relationships < https://www.fda.gov/media/71277/download>

Modeling: PBPK Format and Content Guidance



Physiologically Based Pharmacokinetic Analyses — Format and Content

Guidance for Industry

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Email: druginfo@fda.hhs.gov
https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

August 2018
Clinical Pharmacology

PBPK:

A PBPK analysis uses models and simulations that combine physiology, population, and drug characteristics to mechanistically describe the PK and/or pharmacodynamic (PD) behaviors of a drug.

Topics

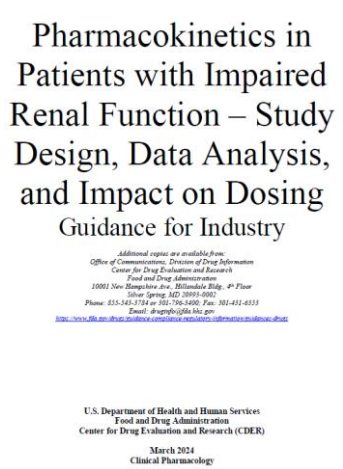
- Introduction
- Background
- Format and Content
  - Executive Summary
  - Introduction
  - Materials and Methods
  - Results
  - Discussion
  - Appendices

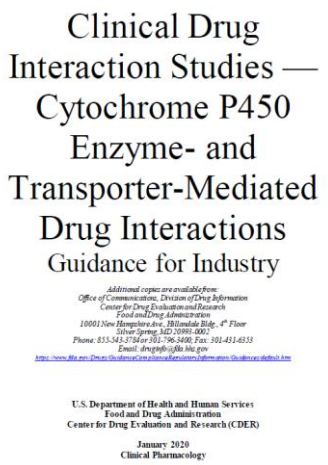
Ref: PBPK format and content guidance < https://www.fda.gov/media/101469/download>

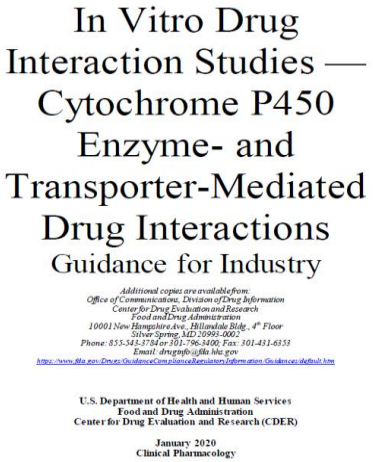
Application of M&S in Clinical Pharmacology (1)

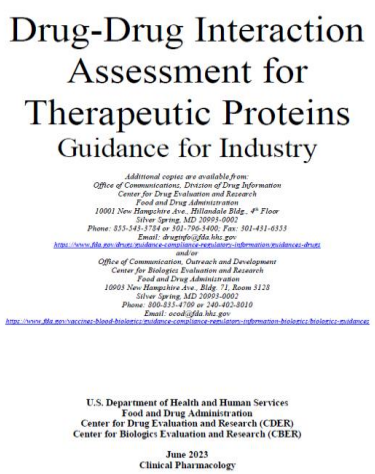
Clinical Pharmacology Considerations

Intrinsic & Extrinsic


Pharmacokinetics in Patients with Impaired Renal Function – Study Design, Data Analysis, and Impact on Dosing
Guidance for Industry
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
March 2024
Clinical Pharmacology


Clinical Drug Interaction Studies — Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactions
Guidance for Industry
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
January 2020
Clinical Pharmacology


In Vitro Drug Interaction Studies — Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactions
Guidance for Industry
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
January 2020
Clinical Pharmacology


Drug-Drug Interaction Assessment for Therapeutic Proteins
Guidance for Industry
U.S. Department of Health and Human Services
Food and Drug Administration
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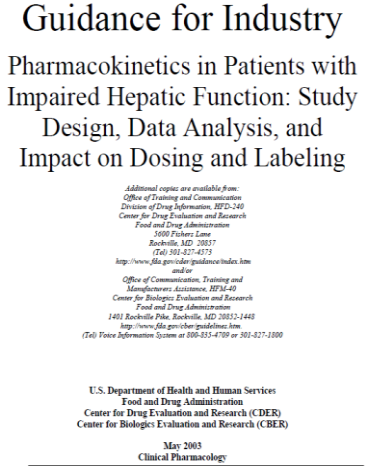
June 2023
Clinical Pharmacology


Guidance for Industry
Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
May 2003
Clinical Pharmacology

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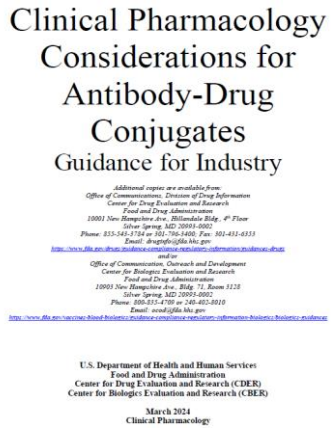
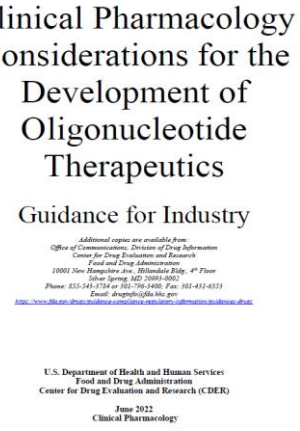
Novel Modality


Clinical Pharmacology Considerations for Antibody-Drug Conjugates
Guidance for Industry
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
March 2024
Clinical Pharmacology


Clinical Pharmacology Considerations for the Development of Oligonucleotide Therapeutics
Guidance for Industry
U.S. Department of Health and Human Services
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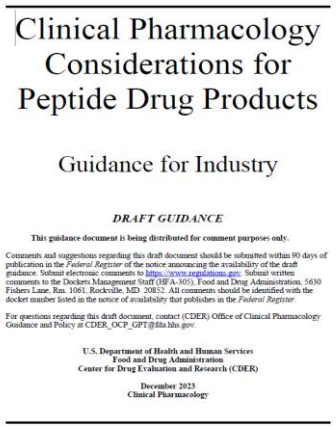
Clinical Pharmacology Considerations for Peptide Drug Products
Guidance for Industry
DRAFT GUIDANCE
This guidance document is being distributed for comment purposes only.
U.S. Department of Health and Human Services
Food and Drug Administration
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December 2023
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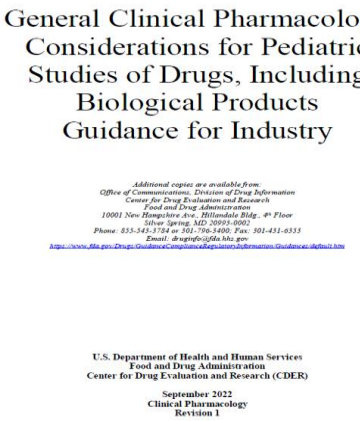
Other Subpopulations


General Clinical Pharmacology Considerations for Pediatric Studies of Drugs, Including Biological Products
Guidance for Industry
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
September 2022
Clinical Pharmacology
Revision 1

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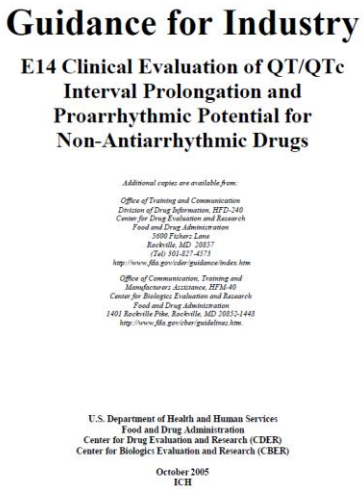
Application of M&S in Clinical Pharmacology (2)

PD Assessment

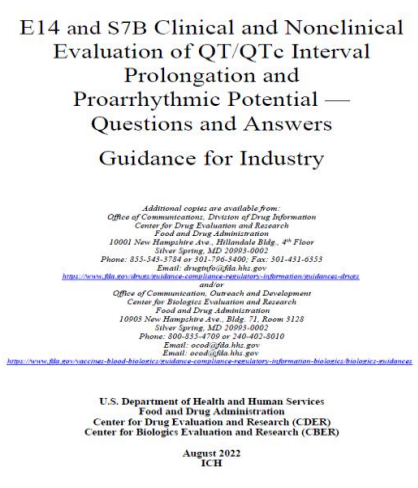


Guidance for Industry

E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

October 2005
ICH



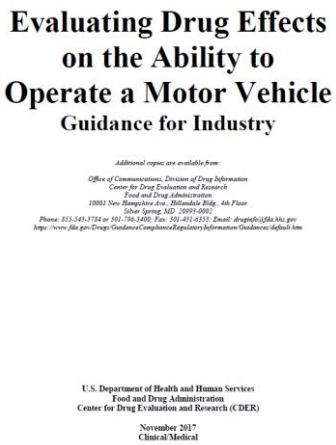
E14 and S7B Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential — Questions and Answers

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

August 2022
ICH

QTc interval prolongation is considered as PD marker to assess proarrhythmic potential for non- arrhythmic drugs. ICH E14 guidance defines the needs, clinical study design, data analysis, and implication for QT assessment. The Q&A highlights the value of CQT analysis.



Evaluating Drug Effects on the Ability to Operate a Motor Vehicle

Guidance for Industry

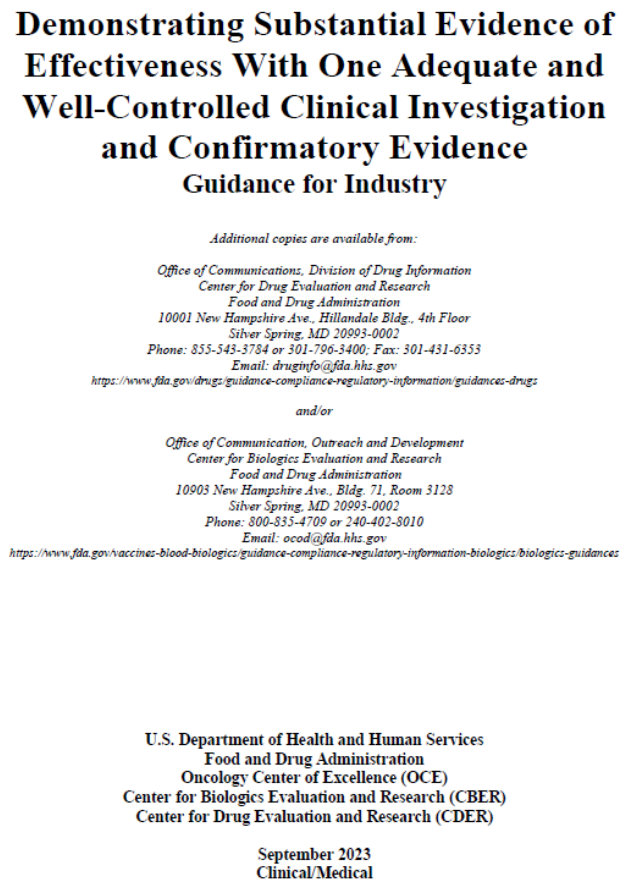
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

November 2017
Clinical/Medical

Driving impairment may be a safety concern for psychoactive drugs. This guidance illustrates the needs and provides instructions on the approach to assess driving impairment as a potential PD marker. In addition, it highlights the ways for labeling the findings.

Application of M&S in Clinical Development (1)

Evidentiary Framework for New Drug Clinical Development



Demonstrating Substantial Evidence of Effectiveness With One Adequate and Well-Controlled Clinical Investigation and Confirmatory Evidence

Guidance for Industry

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https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances

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Food and Drug Administration
Oncology Center of Excellence (OCE)
Center for Biologics Evaluation and Research (CBER)
Center for Drug Evaluation and Research (CDER)

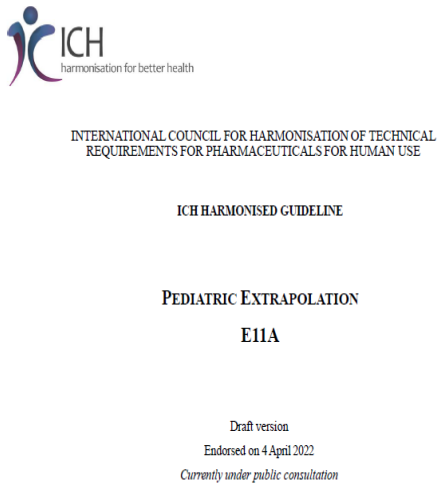
September 2023
Clinical/Medical

Types of Confirmative Evidence:

- Clinical evidence from a related indication.
- Mechanistic or pharmacodynamic evidence.
- Evidence from a relevant animal model
- Evidence from other Members of the same pharmacological class
- Natural history evidence
- Real-world data/evidence
- Evidence from expanded access use of an investigational drug

Application of M&S in Clinical Development (2)

Streamlining Various Clinical Development Programs


ICH
harmonisation for better health

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

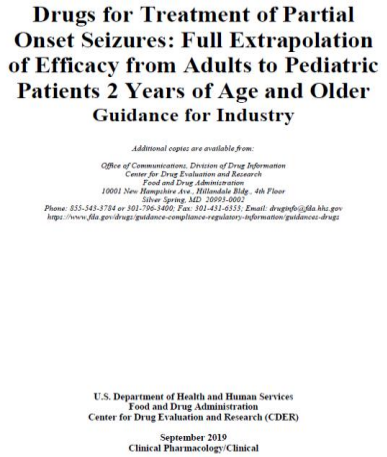
PEDIATRIC EXTRAPOLATION

E11A

Draft version

Endorsed on 4 April 2022

Currently under public consultation


Drugs for Treatment of Partial Onset Seizures: Full Extrapolation of Efficacy from Adults to Pediatric Patients 2 Years of Age and Older
Guidance for Industry

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Center for Drug Evaluation and Research
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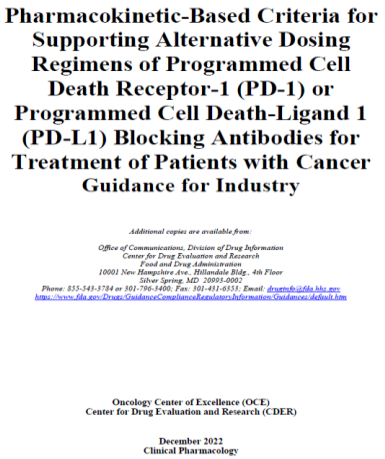
https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

September 2019
Clinical Pharmacology/Clinical


Pharmacokinetic-Based Criteria for Supporting Alternative Dosing Regimens of Programmed Cell Death Receptor-1 (PD-1) or Programmed Cell Death-Ligand 1 (PD-L1) Blocking Antibodies for Treatment of Patients with Cancer
Guidance for Industry

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Food and Drug Administration
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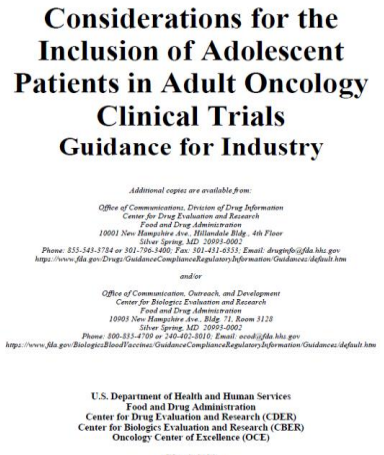
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353; Email: druginfo@fda.hhs.gov
https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

Oncology Center of Excellence (OCE)
Center for Drug Evaluation and Research (CDER)

December 2022
Clinical Pharmacology


Considerations for the Inclusion of Adolescent Patients in Adult Oncology Clinical Trials
Guidance for Industry

Additional copies are available from:

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U.S. Department of Health and Human Services
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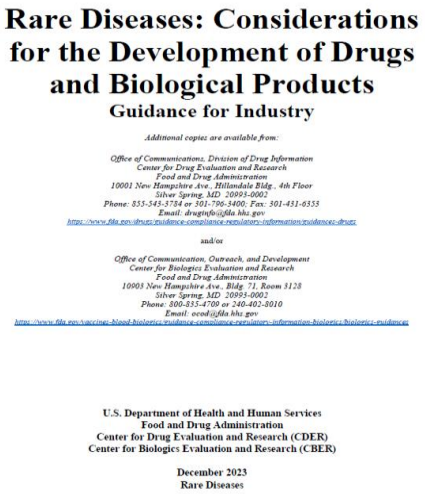
Center for Biologics Evaluation and Research (CBER)
Oncology Center of Excellence (OCE)

March 2019
Clinical/Medical


Rare Diseases: Considerations for the Development of Drugs and Biological Products
Guidance for Industry

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Center for Drug Evaluation and Research (CDER)
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December 2023
Rare Diseases

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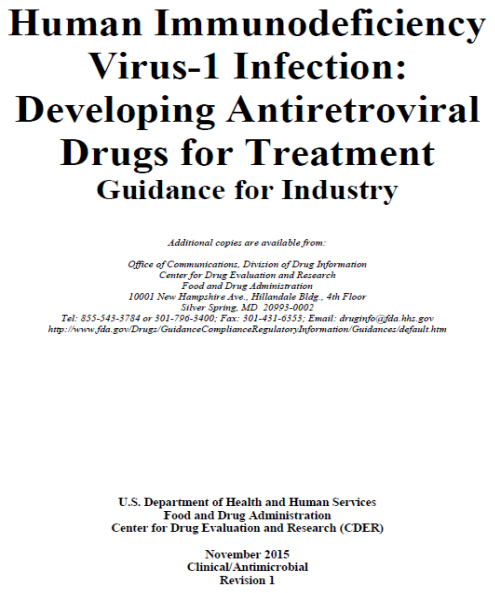
These guidance documents are prepared either based on M&S findings or support the use of M&S as alternative approaches to streamline new drug development for innovation.

Application of M&S in Clinical Development (3)

Applicable in Multiple Therapeutic Areas



Human Immunodeficiency Virus-1 Infection: Developing Antiretroviral Drugs for Treatment
Guidance for Industry

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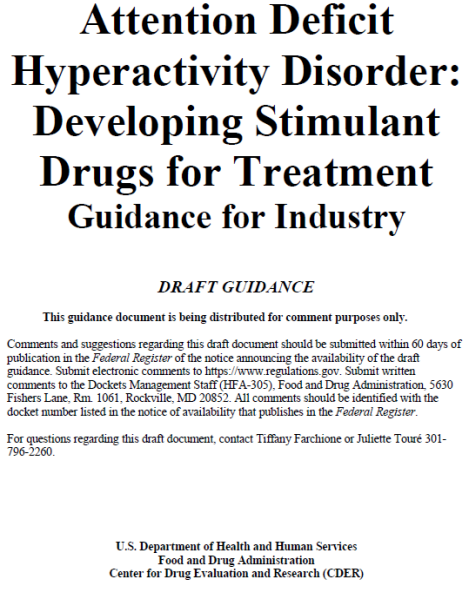
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

November 2015
Clinical/Antimicrobial
Revision 1

Antiviral Drug Development



Attention Deficit Hyperactivity Disorder: Developing Stimulant Drugs for Treatment
Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

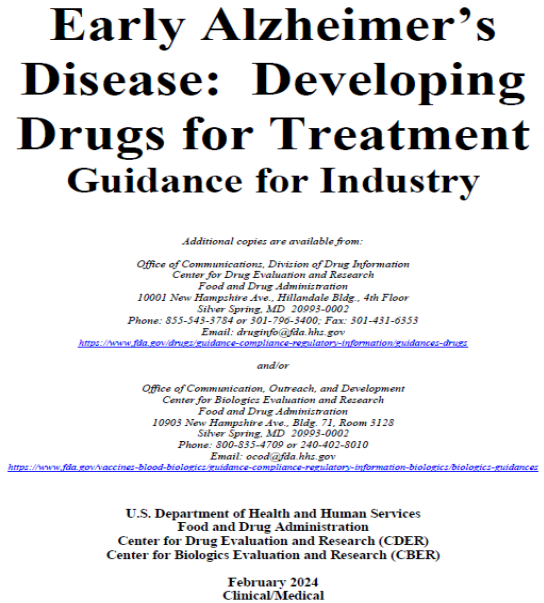
Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact Tiffany Farchione or Juliette Touré 301-796-2260.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

May 2019
Clinical/Medical

Psychiatry Drug Development



Early Alzheimer's Disease: Developing Drugs for Treatment
Guidance for Industry

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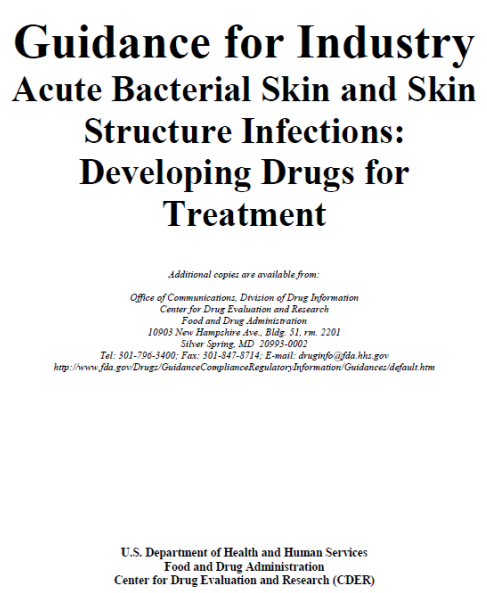
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

February 2024
Clinical/Medical
Revision 2

Neurology Drug Development



Guidance for Industry
Acute Bacterial Skin and Skin Structure Infections: Developing Drugs for Treatment

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

October 2013
Clinical/Antimicrobial

Anti-infective Drug Development

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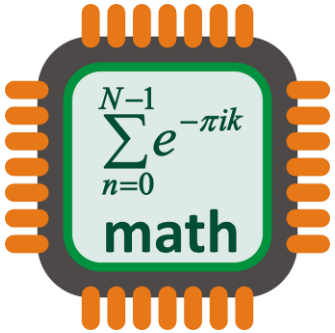
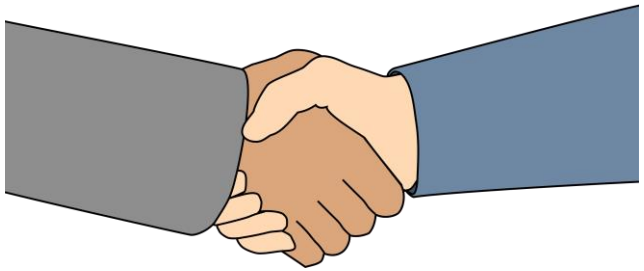
Collaboration to Advance Drug Development

Novel Tools



Development Standards and Practices

Expanded Applications



New Modalities

Opportunities for New Policy Development

Take Home Messages

- Quantitative clinical pharmacology plays critical roles in promoting innovation in new drug development.
- Quantitative clinical pharmacology related guidances are structured at multiple levels
  - MIDD Overarching Guidance
  - Guidance for Specific Methodology
  - Application in Clinical Pharmacology
  - Application in Clinical Development
- Seek feedbacks on needed areas in new policy development

Acknowledgement

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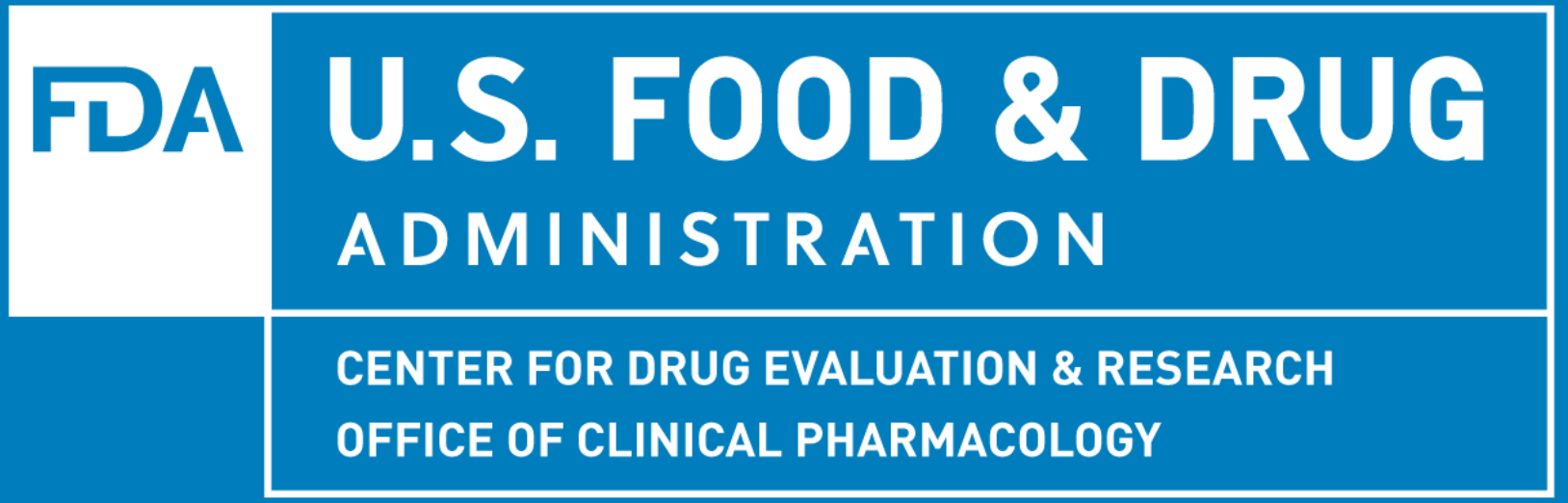
- Dr. Shiew-Mei Huang
- Dr. Issam Zineh,
- DPM members
- OCP members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