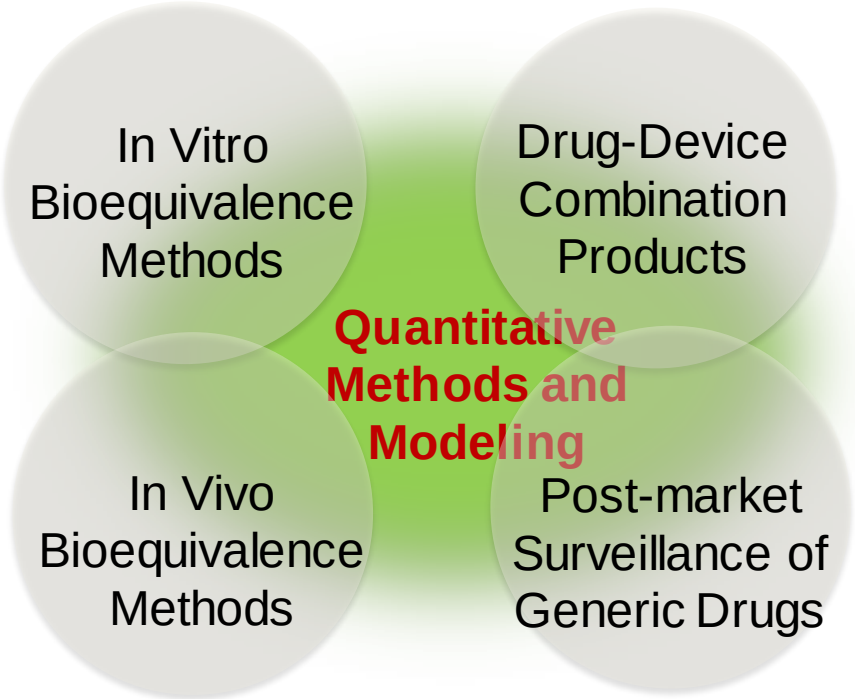
Overview of GDUFA II-funded Modeling and Simulation Grants/Contracts

Liang Zhao, PhD
Division Director
Division of Quantitative Methods & Modeling
Office of Research and Standards, Office of Generic Drugs, CDER/FDA

2021 Annual ACoP Conference Initiatives Public Workshop
November 8-12, 2021

Quantitative Methods & Modeling (QMM) for Generic Drug Development and Approval



Model integrated evidence (MIE) refers to using model generated information such as the virtual bioequivalence (VBE) study results not just to plan a pivotal study but to serve as pivotal evidence

Clin Pharmacol Ther. 2019 Feb;105(2):338-349

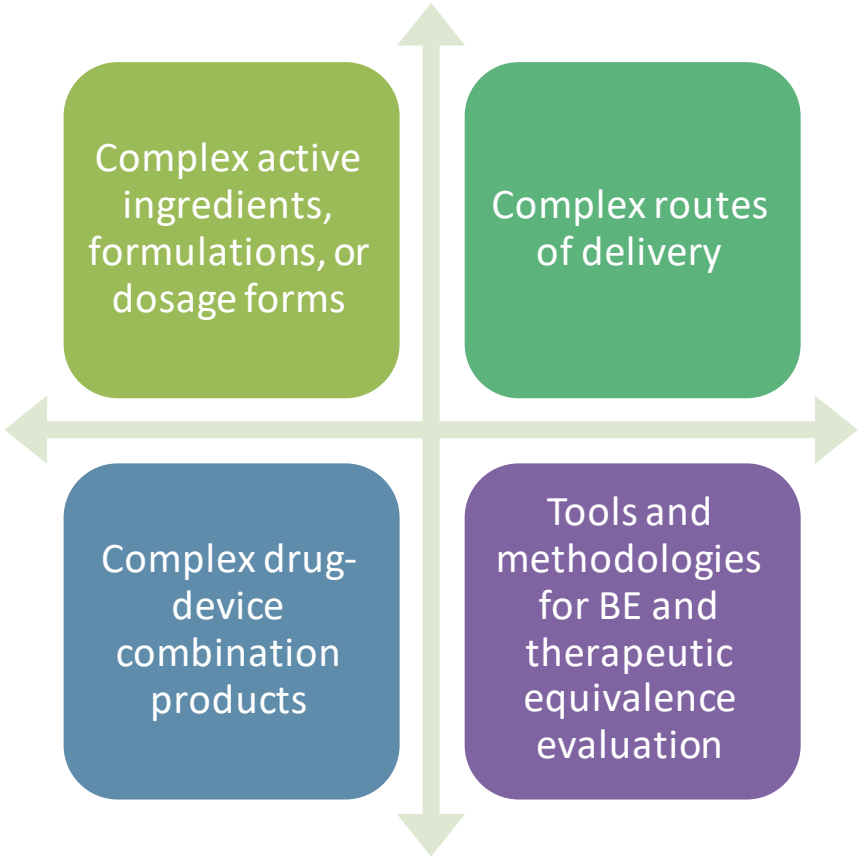
QMM/MIE Impact Various Regulatory Activities in the Office of Generic Drugs (CY 2020), Critically Supported by GDUFA Regulatory Science

	Type	No.	Examples
Regulatory	ANDA Review Consults	15	❖ **Particle size distribution space for BE assessment; dose scale analysis with data censoring; model-based CE BE analysis** ❖ Topical dermatological/orally inhaled/long-acting injectable products ❖ Evaluation of alternative BE approaches to the CE study for locally acting products
	Pre-ANDA Meetings	52	
	Controlled Correspondences	64	
	BE Guidance	11+	❖ PSGs: New/revised guidance on modified release products; use of pAUC as an additional BE metrics (e.g., methylphenidate)
Research	Internal Regulatory Research Projects	56	❖ Assessment of PD endpoints for BE evaluation ❖ BE evaluation methods (e.g., higher-order crossover design, group/batch effects) ❖ BE study interruption during COVID-19 pandemic
	New Contracts and Grants in GDUFA II since 10/2017	35	❖ Development of model-informed BE for complex generic drugs ❖ Modeling platform development (e.g., long acting injectables, sparse sampling) ❖ Development of PBPK model for locally-acting drug products ❖ Characterizing safety and efficacy of generic drugs, and expanding BCS class 3 waivers

Clearance Note: Slides Cleared for 2021 GDUFA Regulatory Science Workshop Presentation

ANDA, abbreviated new drug application; BE, bioequivalence; CE, clinical endpoint; PK, pharmacokinetic; PD, pharmacodynamics; PBPK, physiologically based PK; PSG, product-specific guidance; BCS, Biopharmaceutics Classification System; pAUC, partial area under the curve.

GDUFA II Regulatory Science Priorities



QMM Related GDUFA II Funded Grants/Contracts (1)

GDUFA II Regulatory Science Priorities		Grants/Contracts	Institute
A - Complex active ingredients, formulations, or dosage forms	Support BE demonstration of suspended and colloidal drug products	PK/PD of topically administered ophthalmic IOP drug formulations in rabbits	Absorption Systems
		Physiologically based pharmacokinetic model for drugs encapsulated into liposomes	University of Buffalo
	Develop predictive in vitro BE methods for long-acting injectable (LAI) drug products	Data-fusion based platform development of population PKPD modeling and statistical analysis for bioequivalence assessment of long-acting injectable products	University of Massachusetts
		Development of PBPK simulation for long-acting injectable microspheres	Simulations Plus
		Computational drug delivery: leveraging predictive models to develop bioequivalent generic long-acting injections	Qrono, Inc.
		Pharmacometric modeling and simulation for evaluation of bioequivalence for leuprolide acetate injection	University of Utah

QMM Related GDUFA II Funded Grants/Contracts (2)

GDUFA II Regulatory Science Priorities		Grants/Contracts	Institute
B - Complex routes of delivery	Improve Physiologically Based Pharmacokinetic (PBPK) models of drug absorption via complex routes of delivery	MIDD Approach to Identify Critical Quality Attributes and Specifications for Generic Nanotechnology Products	IQSP - Institute of Quantitative Systems Pharmacology
		Physiologically based pharmacokinetic model for drugs encapsulated into liposomes	University of Buffalo
		Enhancing the reliability, efficiency, and usability of Bayesian population PBPK modeling	Colorado State University
		Physiologically-based model of the female reproductive tract: vaginal and intrauterine delivery components	University at Buffalo
		PBPK and Population Modeling Seamlessly Linked to Clinical Trial Simulation in an Open-Source Software Platform	Children's Hospital of Los Angeles
		Development and validation of dermal PBPK modeling platform toward virtual bioequivalence assessment considering population variability	Simcyp, Ltd.
		Physiologically based biopharmaceutics and pharmacokinetics of drug products for dermal absorption in humans	University of South Australia
		Formulation drug product quality attributes in dermal physiologically-based pharmacokinetic models for topical dermatological drug products and transdermal delivery systems (U01)	Simulations Plus, Inc.
		Formulation drug product quality attributes in dermal physiologically-based pharmacokinetic models for topical dermatological drug products and transdermal delivery systems (U01)	University of Queensland

QMM Related GDUFA II Funded Grants/Contracts (3)

GDUFA II Regulatory Science Priorities		Grants/Contracts	Institute
B - Complex routes of delivery	Improve PBPK models of drug absorption via complex routes of delivery	Characterization of Key System Parameters of Mechanistic Dermal PBPK Models in Various Skin Diseases and Performance Verification of the Model Using Observed Local and Systemic Concentrations	Simcyp, Ltd.
		Development of a multi-functional, multi-purpose quantitative tool for dermal PBPK modeling	Simulations Plus, Inc
		An Integrated Multiscale-Multiphysics Modeling and Simulation of Ocular Drug Delivery with Whole-Body Pharmacokinetic Response with Kay Sun at CFD Corporation	CFD Corporation
		PBPK modeling and simulation for ocular dosage forms	Simulations Plus
		Simulation Plus Ophthalmic ointment implemenation	Simulations Plus, Inc.
		An integrated multiscale-multiphysics modeling framework for evaluation of generic ophthalmic drug products	CFD Research Corporation
		Computational Biology (Cobi) Tools as a Framework for Physiologically-Based Pharmacokinetic/Pharmacodynamic Model Extrapolation from Rabbit to Human for Ophthalmic Drug Products	CFD Research Corporation
		Development and Validation of a PBPK/PD Modeling Strategy for Ophthalmic Drug Products to Support Translation from Preclinical Species to Human	Simulations Plus, Inc.
		Development of hybrid CFD-PBPK models for absorption of intranasal corticosteroids	Applied Research Associates, Inc.
		A predictive multiscale computational tool for simulation of lung absorption and pharmacokinetics and optimization of pulmonary drug delivery	CFD Corporation

QMM Related GDUFA II Funded Grants/Contracts (4)

GDUFA II Regulatory Science Priorities		Grants/Contracts	Institute
B - Complex routes of delivery	Improve PBPK models of drug absorption via complex routes of delivery	Evaluating Relationships Between In Vitro Nasal Spray Characterization Test Metrics for Bioequivalence and Nasal Deposition In Silico and In Vitro	Virginia Commonwealth University
		Development of Computational Models to Predict Delivery of Inhalation Drug Powders: from Deagglomeration in Devices to Deposition in Airways	University of Sydney
		Three-Dimensional Approach for Modeling Nasal Mucociliary Clearance via Computational Fluid Dynamics	North Carolina State University Raleigh
		A cluster-based assessment of drug delivery in asthmatic small airways	University of Iowa
		Modeling Complex Particle Interactions in Dry Powder Inhaler Based Drug Delivery	Princeton University
		A Multiscale Computational Framework for Bioequivalence of Orally Inhaled Drugs	CFD Research Corporation (CFDRC)
		Modifications and Improvements to hybrid CFD-PBPK models for prediction of nasal corticosteroid deposition, absorption and bioavailability	Applied Research Associates
		Computational Fluid Dynamics (CFD) Predictions Of Dry Powder Inhaler (DPI) Regional Deposition In Human Upper And Lower Airways	University of North Carolina at Chapel Hill
		Quantify The Expression Of Metabolizing Enzymes And Transporter Proteins In Lung, Eye And Skin Tissue In Relevant Animal Models And Humans	
		Computational Fluid Dynamics (CFD) Models to Aid the Development of Generic Metered Dose Inhalers	Virginia Commonwealth University

QMM Related GDUFA II Funded Grants/Contracts (5)

GDUFA II Regulatory Science Priorities		Grants/Contracts	Institute
B - Complex routes of delivery	**Expand characterization-based BE for topical dermatological products**	Development and validation of dermal PBPK modeling platform toward virtual bioequivalence assessment considering population variability	Simcyp, Ltd.
		Physiologically based biopharmaceutics and pharmacokinetics of drug products for dermal absorption in humans	University of South Australia
		Formulation drug product quality attributes in dermal physiologically-based pharmacokinetic models for topical dermatological drug products and transdermal delivery systems (U01)	Simulations Plus, Inc.
		Formulation drug product quality attributes in dermal physiologically-based pharmacokinetic models for topical dermatological drug products and transdermal delivery systems (U01)	University of Queensland
		Characterization of Key System Parameters of Mechanistic Dermal PBPK Models in Various Skin Diseases and Performance Verification of the Model Using Observed Local and Systemic Concentrations	Simcyp, Ltd.
		Development of a multi-functional, multi-purpose quantitative tool for dermal PBPK modeling	Simulations Plus, Inc

QMM Related GDUFA II Funded Grants/Contracts (6)

GDUFA II Regulatory Science Priorities		Grants/Contracts	Institute
B - Complex routes of delivery	**Expand characterization-based BE for non-solution ophthalmic products**	An Integrated Multiscale-Multiphysics Modeling and Simulation of Ocular Drug Delivery with Whole-Body Pharmacokinetic Response with Kay Sun at CFD Corporation	CFD Corporation
		PBPK modeling and simulation for ocular dosage forms	Simulations Plus
		Simulation Plus Ophthalmic ointment implementation	Simulations Plus, Inc.
		An integrated multiscale-multiphysics modeling framework for evaluation of generic ophthalmic drug products	CFD Research Corporation
		Computational Biology (Cobi) Tools as a Framework for Physiologically-Based Pharmacokinetic/Pharmacodynamic Model Extrapolation from Rabbit to Human for Ophthalmic Drug Products	CFD Research Corporation
		Development and Validation of a PBPK/PD Modeling Strategy for Ophthalmic Drug Products to Support Translation from Preclinical Species to Human	Simulations Plus, Inc.

QMM Related GDUFA II Funded Grants/Contracts (7)

GDUFA II Regulatory Science Priorities		Grants/Contracts	Institute
B - Complex routes of delivery	Develop more efficient alternatives to the use of forced expiratory volume in one second (FEV1) comparative clinical endpoint BE studies for inhaled corticosteroids	Pharmacokinetic Comparison of Locally Acting Inhaled Drug Products	University of Florida
		Investigate the sensitivity of pharmacokinetics in detecting differences in physicochemical properties of the active in suspension nasal products for local action	University of Florida
		Development of hybrid CFD-PBPK models for absorption of intranasal corticosteroids	Applied Research Associates, Inc.
		A predictive multiscale computational tool for simulation of lung absorption and pharmacokinetics and optimization of pulmonary drug delivery	CFD Corporation
		Evaluating Relationships Between In Vitro Nasal Spray Characterization Test Metrics for Bioequivalence and Nasal Deposition In Silico and In Vitro	Virginia Commonwealth University
		Development of Computational Models to Predict Delivery of Inhalation Drug Powders: from Deagglomeration in Devices to Deposition in Airways	University of Sydney
		Three-Dimensional Approach for Modeling Nasal Mucociliary Clearance via Computational Fluid Dynamics	North Carolina State University Raleigh
		A cluster-based assessment of drug delivery in asthmatic small airways	University of Iowa
		Modeling Complex Particle Interactions in Dry Powder Inhaler Based Drug Delivery	Princeton University
		A Multiscale Computational Framework for Bioequivalence of Orally Inhaled Drugs	CFD Research Corporation (CFDRC)
		Modifications and Improvements to hybrid CFD-PBPK models for prediction of nasal corticosteroid deposition, absorption and bioavailability	Applied Research Associates
		Computational Fluid Dynamics (CFD) Predictions Of Dry Powder Inhaler (DPI) Regional Deposition In Human Upper And Lower Airways	University of North Carolina at Chapel Hill
		Quantify The Expression Of Metabolizing Enzymes And Transporter Proteins In Lung, Eye And Skin Tissue In Relevant Animal Models And Humans	

QMM Related GDUFA II Funded Grants/Contracts (8)

GDUFA II Regulatory Science Priorities		Grants/Contracts	Institute
D - Tools and methodologies for BE and therapeutic equivalence evaluation	**Improve quantitative pharmacology and BE trial simulation to optimize design of BE studies for complex generic drug products**	Data-fusion based platform development of population PKPD modeling and statistical analysis for bioequivalence assessment of long-acting injectable products	University of Massachusetts
		Development of PBPK simulation for long-acting injectable microspheres	Simulations Plus
		Computational drug delivery: leveraging predictive models to develop bioequivalent generic long-acting injections	Qrono, Inc.
		Pharmacometric modeling and simulation for evaluation of bioequivalence for leuprolide acetate injection	University of Utah
		Evaluation of model-based bioequivalence statistical approaches for sparse design PK studies	Inst Nat Sante Et La Recherche Medicale (INSERM)
		Evaluation and development of model-based bioequivalence analysis strategies	Uppsala University
		Development of model-informed bioequivalence evaluation strategies for long-acting injectable products	Uppsala University
		Evaluation of Model-Based Bioequivalence (MBBE) statistical approaches for sparse designs PK studies	Inst Nat Sante Et La Recherche Medicale (INSERM)

QMM Related GDUFA II Funded Grants/Contracts (9)

GDUFA II Regulatory Science Priorities		Grants/Contracts	Institute
D - Tools and methodologies for BE and therapeutic equivalence evaluation	Integrate predictive dissolution, PBPK and Pharmacokinetic/Pharmacodynamic (PK/PD) establishing BE	PBPK and Population Modeling Seamlessly Linked to Clinical Trial Simulation in an Open-Source Software Platform	Children's Hospital of Los Angeles
		Robust in vitro/in silico Model to Accelerate Generic Drug Product Development for the Oral Cavity Route of Administration	St. Louis College of Pharmacy
		Pharmacometric modeling and simulation for generic drug substitutability evaluation and post marketing risk assessment	University of Maryland
		Population pharmacokinetic and pharmacodynamic, dose-toxicity modeling and simulation for narrow therapeutic index (NTI) drugs	University of Maryland
		Pharmacokinetic and pharmacodynamic (PK-PD) studies of cardiovascular drugs	University of Florida
		A model and system based approach to efficacy and safety questions related to generic substitution	University of Florida
		Generic Drug Substitution in Special Populations	Auburn University
		Pharmacometric modeling of immunosuppressants for evaluation of bioequivalence criteria	University of Utah
		Pharmacokinetic pharmacodynamic studies of methylphenidate extended release products in pediatric attention deficit hyperactivity disorder	Massachusetts General Hospital

QMM Related GDUFA II Funded Grants/Contracts (10)

GDUFA II Regulatory Science Priorities		Grants/Contracts	Institute
D - Tools and methodologies for BE and therapeutic equivalence evaluation	Integrate predictive dissolution, PBPK and Pharmacokinetic/Pharmacodynamic (PK/PD) establishing BE	Research Proposal to better understand risk mitigation in the evaluation of relative bioavailability of pediatric generic products	University of Birmingham, UK
		Batch-to-Batch Variability: Exploring Solutions for Generic BE Pathway	UMD
		Prediction of In Vivo Performance for Oral Solid Dosage Forms	University of Michigan
		In Vivo Predictive Dissolution (IPD) to Advance Oral Product Bioequivalence (BE) Regulation	University of Michigan
		Design, Development, Implementation and Validation of a Mechanistic Physiologically-based Pharmacokinetic (PBPK) Framework for the Prediction of the In Vivo Behaviour of Supersaturating Drug Products	Simcyp, Ltd.
		Characterizing safety and efficacy of brand and generic drugs used to treat hypothyroidism among patients who switch therapy formulation	Yale-Mayo CERSI
		Use of instrumental variable approaches to assess the safety and efficacy of brand-name and generic drugs used to treat hypothyroidism	Yale-Mayo CERSI
		Characterizing use, safety and efficacy of brand-name and generic drugs used to treat hypothyroidism	Yale-Mayo CERSI
		Using PBPK To Evaluate The Impact Of Permeation Change Caused By Excipients On The Bioequivalence Assessment For BCS Class III Drugs	Certara UK, LTD

QMM Related GDUFA II Funded Grants/Contracts (11)

GDUFA II Regulatory Science Priorities		Grants/Contracts	Institute
D - Tools and methodologies for BE and therapeutic equivalence evaluation	Expansion of BCS III biowaivers	Using PBPK To Evaluate The Impact Of Permeation Change Caused By Excipients On The Bioequivalence Assessment For BCS Class III Drugs	Certara UK, LTD
	Leverage large data sets for regulatory decisions & post-market surveillance	Developing Tools Based on Text Analysis and Machine Learning to Enhance PSG Review Efficiency	Drexel University
		Software Development Services for Bioequivalence Review Assistance Tool	FUTREND Technology Inc
		Molecular Properties of Excipients	University of California San Francisco
		Novel approaches for confounding control in observational studies of generic drugs	Brigham & Women's Hospital
		Comparative Surveillance of Generic Drugs by Machine Learning	Marshfield Clinic, Inc.
		Structural nested models for assessing the safety and effectiveness of generic drugs	Johns Hopkins University

U.S. FOOD & DRUG ADMINISTRATION

Combined Outcomes with GDUFA I

Locally-Acting PBPK Modeling

Outcomes

- 45 Journal articles
- 52 Presentations
- 34 Posters
- 2 PSGs

Grant #	Study Title	Institute	Start Date	End Date
1U01FD005201	Development of hybrid CFD-PBPK models for absorption of intranasal corticosteroids	Applied Research Associates, Inc.	9/10/2014	2/28/2018
1U01FD005214	A predictive multiscale computational tool for simulation of lung absorption and pharmacokinetics and optimization of pulmonary drug delivery	CFD Corporation	9/10/2014	3/28/2018
1U01FD005219	An integrated multiscale-multiphysics modeling and simulation of ocular drug delivery with whole-body pharmacokinetic response	CFD Corporation	9/10/2014	3/31/2018
1U01FD005206	Physiologically based pharmacokinetic model for drugs encapsulated into liposomes	University of Buffalo	9/10/2014	5/31/2018
1U01FD005225	Development and validation of dermal PBPK modeling platform toward virtual bioequivalence assessment considering population variability	Simcyp, Ltd.	9/10/2014	8/31/2018
1U01FD005211	PBPK modeling and simulation for ocular dosage forms	Simulations Plus	9/10/2014	8/31/2018
1U01FD005232	Physiologically based biopharmaceutics and pharmacokinetics of drug products for dermal absorption in humans	University of South Australia	9/10/2014	2/28/2019
HHSF223201810255P	Simulation Plus Ophthalmic ointment implementation	Simulations Plus, Inc.	8/21/2018	11/30/2019
1U01FD005838	Enhancing the reliability, efficiency, and usability of Bayesian population PBPK modeling	Colorado State University	9/10/2016	8/31/2020
HHSF223201810144C	Evaluating Relationships Between In Vitro Nasal Spray Characterization Test Metrics for Bioequivalence and Nasal Deposition In Silico and In Vitro	Virginia Commonwealth University	9/28/2018	7/30/2021
1U01FD006525	Development of Computational Models to Predict Delivery of Inhalation Drug Powders: from Deagglomeration in Devices to Deposition in Airways	University of Sydney	9/1/2018	8/31/2021
1U01FD006526	Formulation drug product quality attributes in dermal physiologically-based pharmacokinetic models for topical dermatological drug products and transdermal delivery systems (U01)	Simulations Plus, Inc.	9/1/2018	8/31/2021

Quantitative Clinical Pharmacology

Outcomes

- 27 Journal articles
- 48 Presentations
- 26 Posters
- 38 PSGs
- 1 General guidance

Grant #	Study Title	Institute	Start Date	End Date
1U01FD005192	Pharmacometric modeling and simulation for generic drug substitutability evaluation and post marketing risk assessment	University of Maryland	9/10/2014	2/28/2018
1U01FD005188	Population pharmacokinetic and pharmacodynamic, dose-toxicity modeling and simulation for narrow therapeutic index (NTI) drugs	University of Maryland	9/10/2014	2/28/2018
1U01FD005235	Pharmacokinetic and pharmacodynamic (PK-PD) studies of cardiovascular drugs	University of Florida	9/10/2014	8/31/2018
3U01FD005210-03S1	A model and system based approach to efficacy and safety questions related to generic substitution	University of Florida	9/10/2014	8/31/2018
1U01FD005444	Data-fusion based platform development of population PKPD modeling and statistical analysis for bioequivalence assessment of long-acting injectable products	University of Massachusetts	9/15/2015	8/31/2018
1U01FD005463	Development of PBPK simulation for long-acting injectable microspheres	Simulations Plus	9/15/2015	8/31/2018
1U01FD005875	Generic Drug Substitution in Special Populations	Auburn University	9/5/2016	8/31/2018
HHSF223201610110C	Evaluation of model-based bioequivalence statistical approaches for sparse design PK studies	Inst Nat Sante Et La Recherche Medicale (INSERM)	9/29/2016	3/30/2019
HHSF223201510102C	Computational drug delivery: leveraging predictive models to develop bioequivalent generic long-acting injections	Qrono, Inc.	9/14/2015	10/31/2019
1U01FD005191	Pharmacometric modeling of immunosuppressants for evaluation of bioequivalence criteria	University of Utah	9/10/2014	2/29/2020

Oral Absorption Models and BE

Outcomes

- 36 Journal articles
- 23 Presentations
- 41 Posters
- 17 PSGs
- 4 General guidances

Grant #	Study Title	Institute	Start Date	End Date
HHSF223201310144C	Prediction of In Vivo Performance for Oral Solid Dosage Forms	University of Michigan	9/27/2013	11/15/2017
3U01FD004979-02S3-P2	Effect of Excipient Transporter Interactions on BCS Class Drugs	University of California San Francisco	4/15/2014	3/31/2018
HHSF223201610004I-HHSF22301001T	Evaluation of formulation dependence of drug-drug interaction with proton pump inhibitors (PPIs) for oral extended-release drug products	Biopharma Services USA	9/19/2016	9/18/2018
HHSF223201510157C	In Vivo Predictive Dissolution (IPD) to Advance Oral Product Bioequivalence (BE) Regulation	University of Michigan	9/30/2015	9/30/2018
HHSF223201710137C	Phase behavior and transformation kinetics of a poorly water soluble weakly basic drug upon transit from low to high pH conditions	Purdue University	9/29/2017	3/28/2019
1U01FD005259	Formulation, processing and performance interrelationship for amorphous solid dispersions	Purdue University	9/10/2014	8/31/2019
HHSF223201510146C	Wireless Sampling Pill to Measure in Vivo Drug Dissolution in GI Tract and Computational Model To Distinguish Meaningful Product Quality Differences and Ensure Bioequivalence (BE) in Patients	University of Michigan	9/30/2015	8/31/2020
1U01FD005865	Design, Development, Implementation and Validation of a Mechanistic Physiologically-based Pharmacokinetic (PBPK) Framework for the Prediction of the In Vivo Behaviour of Supersaturating Drug Products	Simcyp, Ltd.	9/10/2016	8/31/2020

Patient Substitution of Generic Drugs

Outcomes

- 30 Journal articles
- 12 Presentations
- 13 Posters

Grant #	Study Title	Institute	Start Date	End Date
1U01FD004899	Bioequivalence and Clinical Implications of Generic Bupropion	Washington University	9/15/2013	2/28/2018
1U01FD005192	Pharmacometic modeling and simulation for generic drug substitutability evaluation and post marketing risk assessment	University of Maryland	9/10/2014	2/28/2018
1U01FD005875	Generic Drug Substitution in Special Populations	Auburn University	9/5/2016	8/31/2018
1U01FD005235	Pharmacokinetic and pharmacodynamic (PK-PD) studies of cardiovascular drugs	University of Florida	9/10/2014	8/31/2018
3U01FD005210-03S1	A model and system-based approach to efficacy and safety questions related to generic substitution	University of Florida	9/10/2014	8/31/2018
1U01FD005274	Transplant outcomes using generic and brand name immunosuppressants: studying medications used by people who have received kidney and liver transplants	Arbor Research	9/10/2014	8/31/2018
1U01FD005875	Generic Drug Substitution in Special Populations	Auburn University	9/5/2016	8/31/2018
HHSF223201400188C	Characterization of epilepsy patients at-risk for adverse outcomes related to switching antiepileptic drug products	University of Maryland	9/30/2014	9/29/2018
1U01FD005191	Pharmacometric modeling of immunosuppressants for evaluation of bioequivalence criteria	University of Utah	9/10/2014	2/29/2020

Data Analytics

Outcomes

- 23 Journal articles
- 15 Presentations
- 7 Posters

Grant #	Study Title	Institute	Start Date	End Date
3U01FD004979-02S3-P1	Molecular Properties of Excipients	University of California San Francisco	4/15/2014	3/31/2018
1U01FD005555	Novel approaches for confounding control in observational studies of generic drugs	Brigham & Women's Hospital	9/15/2015	8/31/2018
HHSF223201510112C	Comparative Surveillance of Generic Drugs by Machine Learning	Marshfield Clinic, Inc.	9/30/2015	9/29/2018
1U01FD005556	Structural nested models for assessing the safety and effectiveness of generic drugs	Johns Hopkins University	9/15/2015	2/28/2019
1U01FD005938-A11	Characterizing safety and efficacy of brand and generic drugs used to treat hypothyroidism among patients who switch therapy formulation	Yale-Mayo CERSI	5/28/2019	9/30/2020
75F40119C10106	Developing Tools Based on Text Analysis and Machine Learning to Enhance PSG Review Efficiency	Drexel University	9/30/2019	9/29/2021
75F40120F80605	Software Development Services for Bioequivalence Review Assistance Tool	FUTREND Technology Inc	9/30/2020	9/29/2021
75F40119C10106	Developing Tools Based on Text Analysis and Machine Learning to Enhance PSG Review Efficiency	Drexel University	9/30/2019	9/29/2022
1U01FD005938-A10	Use of instrumental variable approaches to assess the safety and efficacy of brand-name and generic drugs used to treat hypothyroidism	Yale-Mayo CERSI	7/20/2018	8/31/2023
1U01FD005938-A2	Characterizing use, safety and efficacy of brand-name and generic drugs used to treat hypothyroidism	Yale-Mayo CERSI	5/5/2017	8/31/2023

Take Home Message

- The GDUFA regulatory science has been advancing and introducing novel quantitative methods and modeling approaches to the community
- Leveraging these new method advancement in drug development offers new opportunities and values

Acknowledgement

- Office of Research and Standards, OGD/CDER/FDA
  - Robert Lionberger, Office Director
  - Lei Zhang, Office Deputy
- All Contributing Scientists, ORS/OGD/CDER/FDA
- All FDA Grantees and Contractors


FDA
U.S. FOOD & DRUG
ADMINISTRATION