The use of model-informed drug development (MIDD) for new and generic drugs has significantly increased over the past several years. The committee will discuss strategies, approaches, and challenges in MIDD with specific focus on two areas. During the morning session, the committee will discuss approaches and evidentiary information needed for applying physiologically-based pharmacokinetic modeling and simulation throughout a drug’s lifecycle. During the afternoon session, the committee will discuss mechanistic model-informed safety evaluation with a focus on drug potential for causing arrhythmias. The Comprehensive in Vitro Proarrhythmia Assay will be discussed as an examplar.

7:30 a.m. Call to Order and Introduction of Committee
Scott Waldman, MD, PhD
Chairperson, PSCP

7:35 a.m. Conflict of Interest Statement
Jennifer Shepherd, RPh
Designated Federal Officer, PSCP

7:45 a.m. Model-Informed Drug Development (MIDD):
Opportunities and Challenges
Issam Zineh, PharmD, MPH
Director, Office of Clinical Pharmacology (OCP)
Office of Translational Sciences (OTS), CDER, FDA

Session I: ROLE FOR PHYSIOLOGICALLY-BASED PHARMACOKINETIC (PBPK) MODELING AND SIMULATION IN DRUG DEVELOPMENT AND REGULATION

8:00 a.m. FDA PRESENTATIONS

Towards Consistent Regulatory Assessment of Physiologically-based Pharmacokinetic (PBPK) Modeling to Support Dosing Recommendations
Ping Zhao, PhD
PBPK Lead, Division of Pharmacometrics OCP, OTS, CDER, FDA

8:20 a.m. Absorption PBPK Modeling and Applications to Support Formulation and Generic Drug Development
Liang Zhao, PhD
Division Director, Division of Quantitative Methods & Modeling Office of Research and Standards Office of Generic Drugs (OGD), CDER, FDA

8:40 a.m. GUEST SPEAKER PRESENTATIONS

PBPK Submissions and Review Experience in European Medicines Agency (EMA) and EMA Draft PBPK Guideline
Anna Nordmark, PhD
Pharmacokinetic Assessor Medical Products Agency, Sweden
Member of the Modelling and Simulation Working Group, European Medicines Agency (EMA) Rapporteur of the EMA PBPK Guideline
## DRAFT AGENDA (CONT.)

### GUEST SPEAKER PRESENTATIONS (CONT.)

<table>
<thead>
<tr>
<th>Time</th>
<th>Presentation</th>
<th>Speaker</th>
<th>Affiliation</th>
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<tbody>
<tr>
<td>9:00 a.m.</td>
<td>Experience, Opportunity, and Challenges in Submitting PBPK Analyses to Regulators, and Comments to EMA and FDA Draft PBPK Guidance Documents</td>
<td>Neil Parrott, PhD</td>
<td>Distinguished Scientist Roche Pharma Research and Early Development Roche Innovation Center Basel, Switzerland Leader, The Innovation &amp; Quality (IQ) Consortium Working Group on PBPK Guidances</td>
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<tr>
<td>9:20 a.m.</td>
<td>Clarifying Questions</td>
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<td>9:35 a.m.</td>
<td>BREAK</td>
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<td>9:45 a.m.</td>
<td>Open Public Hearing Session I</td>
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<tr>
<td>10:15 a.m.</td>
<td>Questions to the Committee/Committee Discussion I</td>
<td></td>
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<td>11:15 a.m.</td>
<td>LUNCH BREAK</td>
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### Session II: MECHANISTIC MODEL-INFORMED SAFETY EVALUATION: COMPREHENSIVE IN VITRO PROARRHYTHMIA ASSAY (CIPA) AS AN EXAMPLE

<table>
<thead>
<tr>
<th>Time</th>
<th>Presentation</th>
<th>Speaker</th>
<th>Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:05 p.m.</td>
<td>Call to Order and Introduction of Committee</td>
<td>Scott Waldman, MD, PhD</td>
<td>Chairperson, PSCP</td>
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<tr>
<td></td>
<td>Conflict of Interest Statement</td>
<td>Jennifer Shepherd, RPh</td>
<td>Designated Federal Officer, PSCP</td>
</tr>
<tr>
<td>12:10 p.m.</td>
<td>FDA PRESENTATION</td>
<td>Christine Garnett, PharmD</td>
<td>Clinical Analyst and QT Lead Division of Cardiovascular and Renal Products Office of Drug Evaluation I, Office of New Drugs, CDER, FDA</td>
</tr>
<tr>
<td>12:30 p.m.</td>
<td>GUEST SPEAKER PRESENTATIONS</td>
<td>Gary Gintant, PhD</td>
<td>Senior Research Fellow Department of Integrative Pharmacology Abbvie</td>
</tr>
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FOOD AND DRUG ADMINISTRATION (FDA)  
Center for Drug Evaluation and Research (CDER)  

*Pharmaceutical Science and Clinical Pharmacology Advisory Committee (PSCP) Meeting*  
March 15, 2017  

**DRAFT AGENDA (CONT.)**

**GUEST SPEAKER PRESENTATIONS (CONT.)**  
12:50 p.m.  
Background and Rationale for Mechanistic Cardiac Electrophysiology Models  
Gary Mirams, PhD  
Sir Henry Dale Fellow  
Centre for Mathematical Medicine and Biology  
University of Nottingham, United Kingdom

1:05 p.m.  
FDA PRESENTATIONS  
CiPA In Silico Modeling Development Strategy and Results  
Zhihua Li, PhD  
Staff Fellow  
Division of Applied Regulatory Science  
OCP, OTS, CDER, FDA

1:20 p.m.  
Phase 1 Electrocardiogram (ECG) Analysis under CiPA, Integration of All CiPA Components, and Potential Implementation Strategy  
David Strauss, MD, PhD  
Division Director  
Division of Applied Regulatory Science  
OCP, OTS, CDER, FDA

1:40 p.m.  
Clarifying Questions

1:55 p.m.  
BREAK

2:05 p.m.  
Open Public Hearing Session II

2:35 p.m.  
Questions to the Committee/Committee Discussion II

3:35 p.m.  
CONCLUDING REMARKS  
Kathleen Uhl, MD  
Director  
OGD, CDER, FDA

3:45 p.m.  
ADJOURNMENT