FY 2020 Generic Drug Regulatory Science Initiatives Public Workshop

Breakout session 4:
Data Analysis and Model-Based Bioequivalence

May 4, 2020

Liang Zhao, Ph.D.
Director, Division of Quantitative Methods and Modeling
Office of Research and Standards, Office of Generic Drugs, CDER, FDA

Expert Discussants

- **Liang Zhao, PhD** – FDA, CDER/OGD/ORS/DQMM, Session moderator
- **Amin Rostami, PhD** – University of Manchester, Centre for Applied Pharmacokinetic Research
- **Andrew Hooker, PhD** – Uppsala University, Department of Pharmaceutical Biosciences
- **Charlie DiLiberti** – Montclair Bioequivalence Services, LLC
- **Glenys Barber, PhD** – University of Manchester
- **Sandra Suarez-Sharp, PhD** – Simulations Plus, Inc.
- **Viera Lukacova, PhD** – Simulations Plus, Inc.
- **Stella C. Grosser, PhD** – FDA, CDER/OTS/OB (Office of Biostatistics)/DBVIII
- **Stephan Schmidt, PhD** – University of Florida, Center for Pharmacometrics & Systems Pharmacology
- **Sid Bhoopathy, PhD** – Absorption Systems
- **Raja Velagapudi, PhD** – Sandoz Pharmaceuticals, Clinical Development (US)
- **Lanyan (Lucy) Fang, PhD** – FDA, CDER/OGD/ORS/DQMM
- **All break out session participants**

Questions for the Expert Discussants

12:50-1:35 PM: How to evaluate data from in vitro studies and which in vivo studies are clinically relevant (eg, how to justify Q1/Q2/Q3 deviation for equivalence assessment)?

Presentations by Charlie DiLiberti and Sid Bhoopathy

1:35-2:05 PM: What are the challenges for industry in implementing modeling and simulation methods to support more efficient regulatory BE pathways (such as alternative to comparative clinical endpoint BE studies)?

Presentation by Amin Rostami

2:05-2:50 PM: What are the emerging expertise/tools in implementing new BE approaches?

Presentation by Andrew Hooker and Stephan Schmidt

Questions from Audience

- For each subject question (~40’): 1-2 presentations followed by discussion
- You can type in questions in the chat box
- When participating in a discussion, please state your name, title, and affiliation
- When asking a question or making a comment, provide as much context as possible

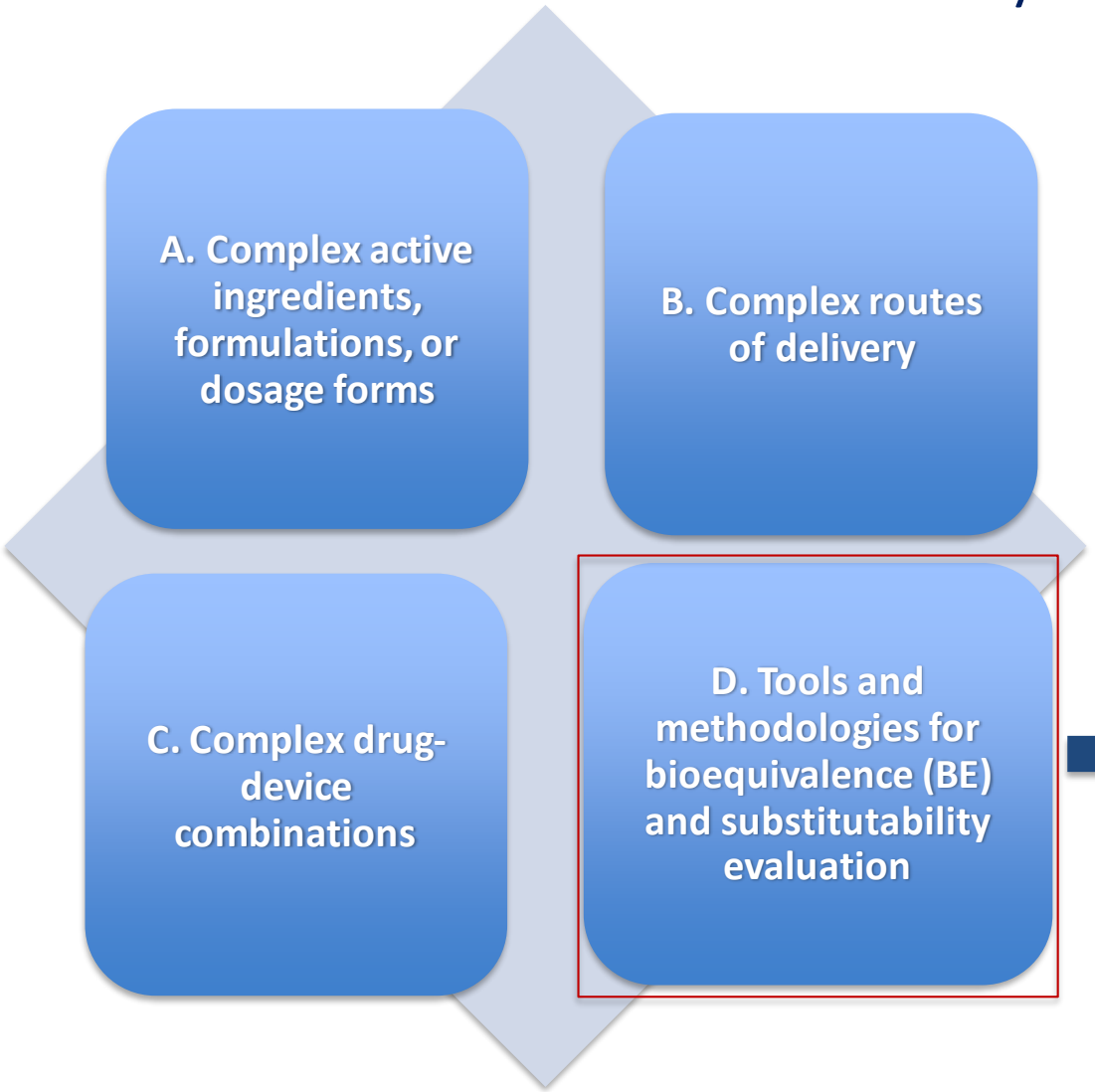
Expert Discussants (Presentation)

Speaker	Topics
Charlie DiLiberti	Modeling to Support Relaxation of Compositional/Microstructural Criteria to Qualify for Streamlined Bioequivalence Approaches
Sid Bhoopathy	Model Informed BE Expanding the Reach and Utility
Amin Rostami	Virtual BE: Requirement for Prudent Use of PBPK in Uncharted Territories
Andrew Hooker	Improved BE Assessment through Model-informed and Model-based strategies
Stephan Schmidt	A Model- and Systems-Based Approach to Efficacy and Safety Questions Related to Generic Substitution
Sandra Suarez-Sharp; Viera Lukacova	Comments to each question


FDA
U.S. FOOD & DRUG
ADMINISTRATION

FY2020 GDUFA Research Science Priorities

that are most relevant to Data Analysis and Model-Based Bioequivalence



- D1. Improve **quantitative pharmacology and BE trial simulation** to optimize design of BE studies for complex generic drug products
- D2. **Integrate predictive dissolution, PBPK and Pharmacokinetic/Pharmacodynamic (PK/PD) models** establishing generic drug bioequivalence standards
- D3. Expand the scientific understanding of the role of excipients in generic drug products to support **the expansion of BCS Class 3 biowaivers** to drug products with differences in formulations larger than currently recommended in FDA guidance
- D4. **Develop methods and integrated technological solutions that will allow FDA to leverage large data sets** (such as bioequivalence study submissions, electronic health records, substitution/utilization patterns, drug safety data, and drug quality data) to support regulatory decisions and improve post-market surveillance of generic drug substitution

https://www.fda.gov/media/132370/download