

Model-Integrated Evidence (MIE) Industry Meeting Pilot Program

January 18, 2024, 1:00 – 3:00 pm EDT

Welcome (5 min)	<p>Welcome and Overview</p> <p>Forest “Ray” Ford, Jr., <i>Captain</i>, United States Public Health Service <i>Pharmacist</i></p> <p>Small Business and Industry Assistance (SBIA) Division of Drug Information (DDI) Office of Communications (OCOMM) Center for Drug Evaluation and Research (CDER)</p>	1:00 - 1:05 pm
Opening Remarks (15 min)	<p>Introduction to MIE Industry Meeting Pilot Program</p> <p>Liang Zhao, PhD <i>Director</i></p> <p>Division of Quantitative Methods and Modeling (DQMM) Office of Research and Standards (ORS) Office of Generic Drugs (OGD) CDER</p>	1:05 - 1:20 pm
Talk 1 (15 min)	<p>Potential Topics for Discussion Through the MIE Industry Meeting Pilot Program</p> <p>Andrew Babiskin, PhD <i>Lead Pharmacokineticist</i>, DQMM ORS OGD CDER</p>	1:20 - 1:35 pm
Talk 2 (15 min)	<p>Considerations and expectations when meeting with the FDA under the Industry Meeting Pilot MIE program</p> <p>Eleftheria Tsakalozou, PhD <i>Senior Pharmacologist (Acting TL)</i>, DQMM ORS OGD CDER</p>	1:35 - 1:50 pm
Talk 3 (15 min)	<p>MIE Pilot Program: Process Overview</p> <p>Maria Monroy-Osorio <i>Regulatory Health Project Manager</i>, ORS OGD CDER</p>	1:50 - 2:05 pm
Panel Discussion (20 min)	<p>Moderator: Lanyan (Lucy) Fang, PhD, <i>Deputy Director</i>, DQMM ORS OGD CDER</p> <p>Panelists:</p> <ul style="list-style-type: none"> • Bhagwant Rege, PhD, <i>Division Director</i>, Division of Biopharmaceutics (DB) Office of New Drug Products (ONDP) Office of Pharmaceutical Quality (OPQ) CDER • Partha Roy, PhD, <i>Director</i>, Office of Bioequivalence (OB) OGD CDER • Robert Lionberger, PhD, <i>Director</i>, ORS OGD CDER • Liang Zhao 	2:05 - 2:25 pm
Speaker Q&A Discussion (30 min)	<p>Moderator: Forest “Ray” Ford, Jr.</p> <p>Panelists:</p> <ul style="list-style-type: none"> • Liang Zhao • Eleftheria Tsakalozou • Andrew Babiskin • Maria Monroy-Osorio • Fang Wu, PhD, <i>Senior Pharmacologist</i>, DQMM ORS OGD CDER • Meng Hu, PhD, <i>Lead Engineer</i>, DQMM ORS OGD CDER 	2:25 - 2:55 pm
Closing Remarks (5 min)	<p>Closing Remarks</p> <p>Robert Lionberger or Lei Zhang</p>	2:55 - 3:00 pm