

The background of the slide is a blurred photograph of laboratory glassware, including beakers and flasks, suggesting a research environment.

We advance research  
to accelerate access to generic drugs.

*| WE ARE THE **GENERIC DRUG PROGRAM***

# Ask Us About

the

# GDUFA Science & Research Program

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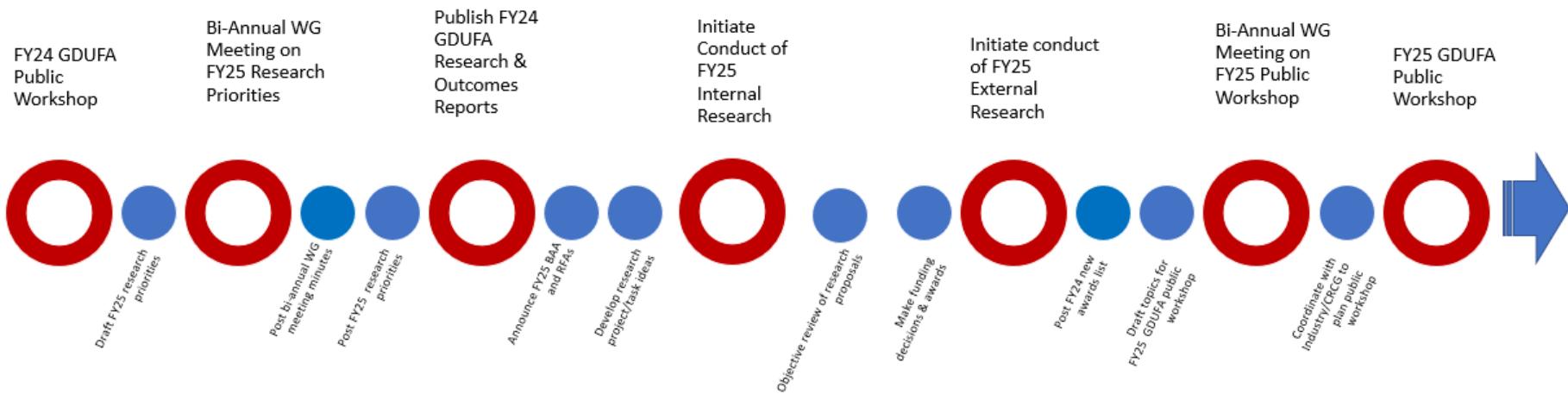
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# GDUFA Research Program



## The GDUFA Research Program Progresses Through a Sequential Series of Activities on an Annual Cycle:



# FDA's Commitments for GDUFA III



## 1. **Conduct Two Meetings Per Year with an Industry-FDA Working Group**

- Discuss current and emerging scientific challenges impacting generic product development or assessment that can be addressed by GDUFA-funded research
- Post minutes of the meeting on FDA's website

# FDA's Commitments for GDUFA III



## 2. **Conduct an Annual Public Workshop**

- Identify what research is needed to address scientific knowledge gaps that limit generic product availability for the American public
- Post the GDUFA science and research priority initiatives for the next fiscal year on FDA's website

# FDA's Commitments for GDUFA III



## 3. **Conduct Internal and External Research**

- Initiate internal research collaborations in priority areas where FDA has relevant scientific expertise and capabilities
- Issue a broad agency announcement (BAA) inviting contract research proposals aligned with the priority areas
- Issue requests for applications (RFAs) inviting grant research proposals for specific research concepts

# FDA's Commitments for GDUFA III



## 3. **Conduct Internal and External Research (continued)**

- Orchestrate objective reviews of all BAA and RFA proposals received to prioritize grants and contracts for funding
- Coordinate financial and administrative logistics to award grants and contracts
- Post the list of new grants and contracts awarded, with brief descriptions and objectives, on FDA's website

# FDA's Commitments for GDUFA III



## 4. Report Annually How GDUFA Research Supports Development, Assessment, and Approval of Generics

- Publish an annual GDUFA science and research report describing impactful research advances on FDA's website
- Publish metrics on regulatory outcomes impacted by GDUFA science and research on FDA's website

# GDUFA Research Program



## 1. Specialized Infrastructure Within FDA

- Laboratory research experts, equipment, and research facilities
- Subject matter experts on the therapeutic performance of specific products (e.g., inhalation, topical, etc.)
- Subject matter experts in quantitative methods and modeling (e.g., pharmacometrics, physiologically based pharmacokinetics modeling and simulation, etc.)
- Specialized expertise in clinical safety and human subject research
- Specialized expertise in operations management for research administration and information systems support

# GDUFA Research Program



## 2. Internal FDA Research Collaborators and Subject Matter Experts

- Advanced laboratory facilities and experts in multiple FDA offices and centers
- Abbreviated new drug application (ANDA) assessors in the Office of Generic Drugs (OGD) and the Office of Pharmaceutical Quality (OPQ)
- GDUFA III implementation research program working group (including OGD + OPQ representatives)

# GDUFA Research Program



## 3. Internal Budget, Finance, Grant/Contract Administration, and Research Governance Partners

- Budget, finance, and grant/contract administration partners in multiple FDA offices
- Center for Drug Evaluation and Research (CDER) research governance council

# GDUFA Research Program



## 4. External Partners

- GDUFA Industry-FDA working group
- Center for Research on Complex Generics (CRCG)



# GDUFA Research Priorities for FY24



- 1. Develop Methods for Generics to Address Impurities such as Nitrosamines**
- 2. Enhance the Efficiency of Equivalence Approaches for Complex Active Ingredients**
- 3. Enhance the Efficiency of BE Approaches for Complex Dosage Forms and Formulations**
- 4. Enhance the Efficiency of BE Approaches for Complex Routes of Delivery**

# GDUFA Research Priorities for FY24



5. Enhance the Efficiency of Equivalence Approaches for Complex Drug-Device Combination Products
6. Improve the Efficiency of BE Approaches for Oral and Parenteral Generic Products
7. Facilitate the Utility of Model-Integrated Evidence (MIE) to Support Demonstrations of BE
8. Expand the Use of Artificial Intelligence (AI) and Machine Learning (ML) Tools

# GDUFA Research Outcomes



## GDUFA Research Outcomes Supporting Generic Product Development and Regulatory Assessment:

- Scientific publications, posters, and presentations
- Scientific workshops, webinars, and training
- Guidances for industry and product-specific guidances
- Generic product development advice via pre-ANDA meetings and controlled correspondences
- ANDA assessment readiness, and support throughout the lifecycle of ANDA assessment, approval, and post-approval

# FY23 GDUFA Science & Research Report



[FY 2023 GDUFA Science and Research Report](#) (PDF - 19 MB)



# Ask Me About GDUFA Research and Funding



- **Regulatory Research under GDUFA:**
  - Generic Drug Research-Related Guidances & Reports



- **GDUFA Research Outcomes**

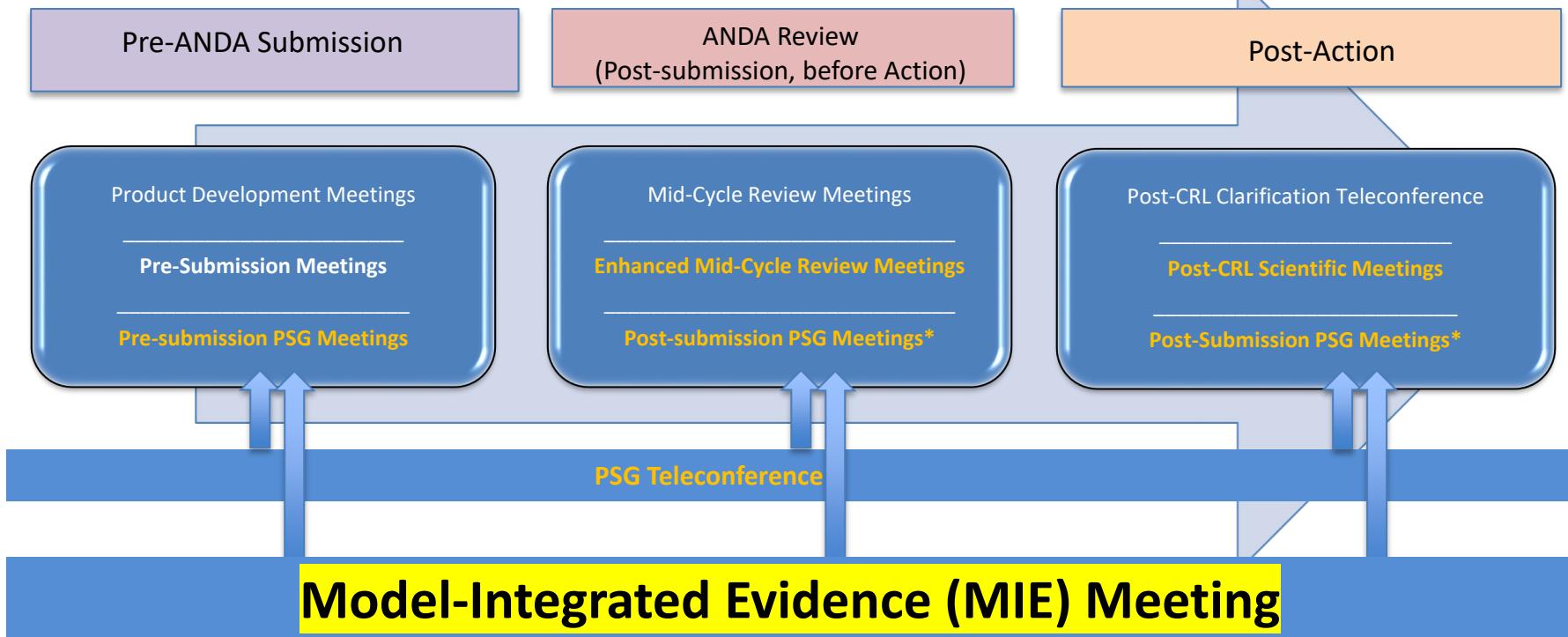


- **Generic Drug Research Collaborations Opportunities**



# Industry Meetings

Slide courtesy of Dr. Lei K Zhang, adapted



# Ask Me About Quantitative Method and Modeling Approaches, Novel In Vitro Approach for supporting BE and Quality of Complex Products



- **All Generic Drug Development Stages:**
  - Model-Integrated Evidence (MIE) Industry Meeting Pilot Between FDA and Generic Drug Applicants
- **Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA Guidance for Industry**
  - Product Development Meeting (Pre-ANDA)
  - Post Complete Response Letter Scientific Meeting (Post-CRL)
- **FDA-EMA Parallel Scientific Advice (PSA) Program for Complex Generic/Hybrid Drug Products**
  - Meetings for prospective applicants to engage with FDA and EMA concurrently



# Ask Me About GDUFA Research and Oral Drug Products



- **Mitigation of Nitrosamine Impurities in Drug Products**

- Safety
- Product control
- Alternative bioequivalence (BE) approach for reformulated products



- **Solid Oral Products**

- Impacts of Excipients and Formulation Designs on BA/BE
- Potential expansion of BCS-based waiver, additional strength waivers
- Global harmonization on BE for IR and MR products
- ICH M13A Bioequivalence for Immediate Release



- **Human Subject Protection in Clinical Trials**

- Special population considerations



A close-up photograph of several hands of different skin tones and ages, symbolizing a diverse community. The hands are shown from the side, overlapping each other.

We care about enhancing  
access to generic drugs

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