
FDA
We advance research
to accelerate access to generic drugs.
WE ARE THE GENERIC DRUG PROGRAM

U.S. FOOD & DRUG ADMINISTRATION

Ask Us About

the

GDUFA Science & Research Program

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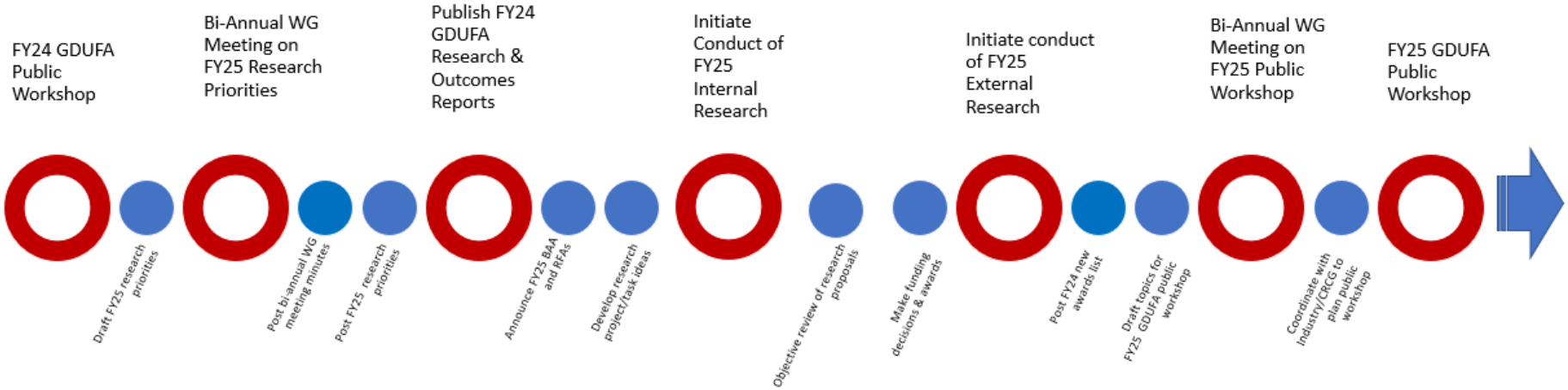
GDUFA Research Program

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

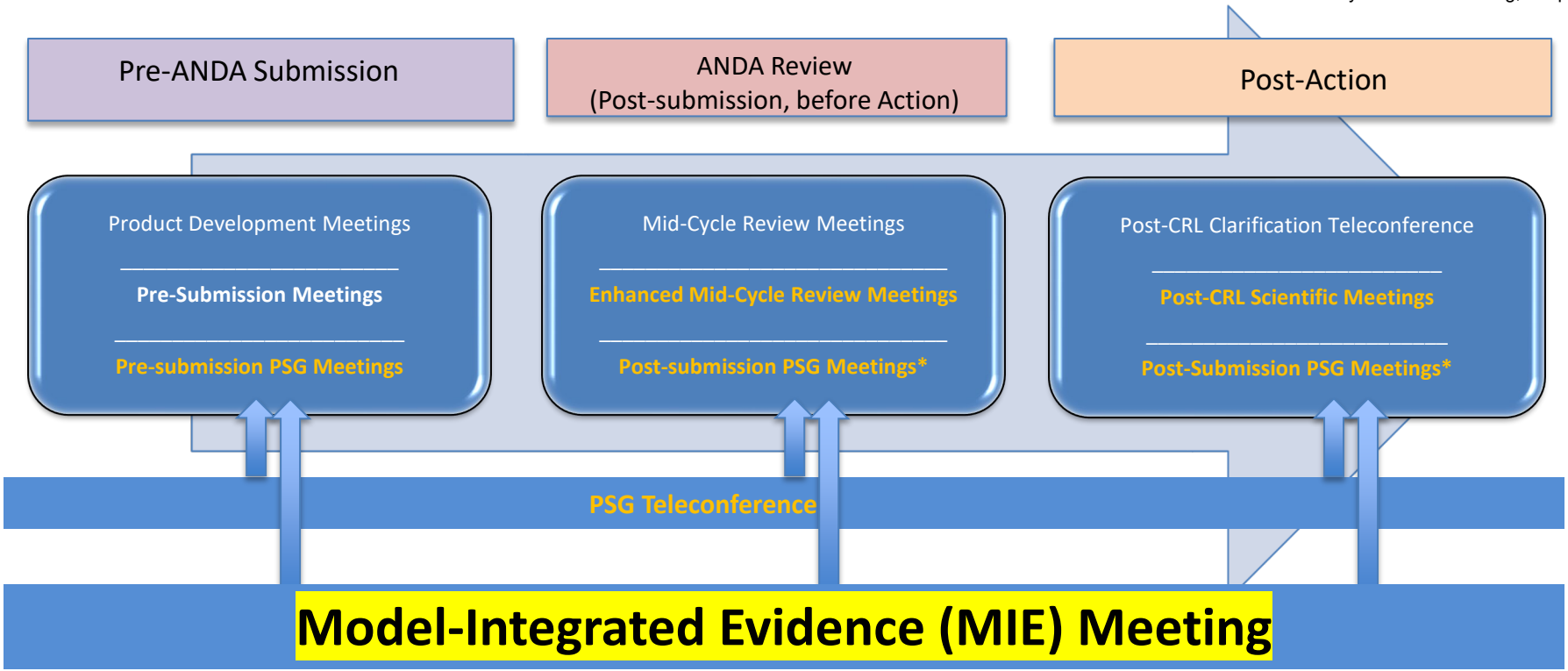
FY 2023 GDUFA Science and Research Report (PDF - 19 MB)

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



CR: complete response; TA: tentative approval; AP: approval; RTR: refuse to receive

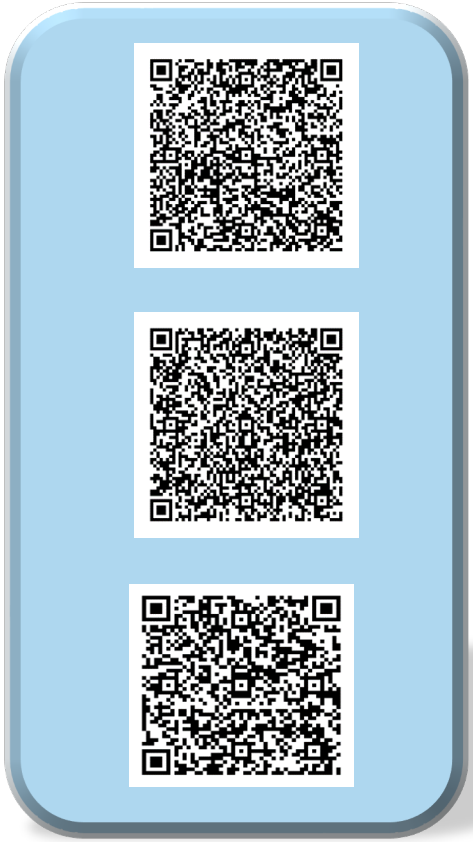
*Depend on the ANDA status, i.e., whether ANDA is under review, post-CRL or TA Action: CR, TA or AP, (during filing, RTR)

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


We care about enhancing access to generic drugs
WE ARE THE GENERIC DRUG PROGRAM