

GDUFA Research Program: Research Priorities to Support Generic Drug Development

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Learning Objectives

- Describe the generic drug science and research program and FDA's commitments under the Generic Drug User Fee Amendments (GDUFA)
- Explain processes for prioritizing scientific initiatives for generic drug development, conducting research, and orchestrating the research program
- Discuss science and research priority initiatives for fiscal year (FY) 2023, and illustrate research outcomes

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



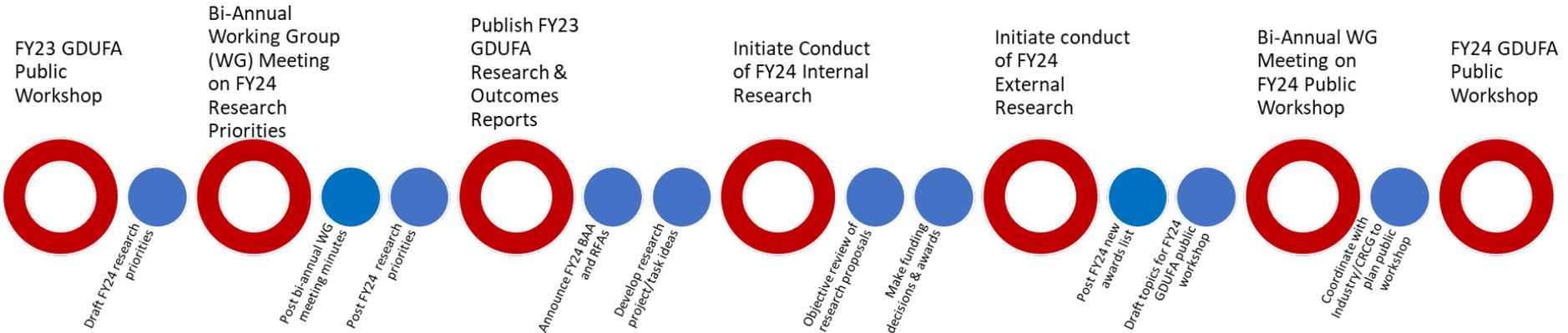
4. External Partners

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

GDUFA Research Program



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



GDUFA Research Priorities for FY23



- 1. Develop Methods for Generics to Address Impurities such as Nitrosamines**
- 2. Enhance the Efficiency of Bioequivalence (BE) 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 FY23



- 5. Enhance the Efficiency of BE 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

Challenge Question #1

The GDUFA science and research program is essential to

- A. Develop novel and efficient BE pathways for generic product development, including complex generics
- B. Ensure that FDA can provide timely and specific scientific advice in pre-ANDA meetings and controlled correspondences
- C. Facilitate patient access to safe, effective, high quality, and affordable generic products, particularly complex generics
- D. All of the above



Challenge Question #2

How are GDUFA science and research priorities established and updated on an annual basis?

- A. Based upon public feedback about what research is needed to address scientific knowledge gaps that limit generic product availability
- B. Based upon comments provided to the FDA through public dockets, during public workshops, in bi-annual meetings of the GDUFA industry-FDA working group, and via the CRCG
- C. Both, A and B



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