Updates on the BsUFA Regulatory Science Research Portfolio

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Scientific Lead of the BsUFA III Regulatory Science Pilot Program

OTBB| OND| CDER| FDA

Research Priorities Dictate the Outcome and Impact Reporting Structure for the Program

Research Priorities That Result in Regulatory Impact:

a. Characterize relationships between product quality attributes (physiochemical or biological) with clinical performance
b. Explore how modernization of analytical technologies could better and/or more efficiently detect relevant quality attributes
c. Define best practices for assessing and reporting product quality attributes
d. Develop alternatives to the comparative clinical immunogenicity assessment(s)
e. Define approaches that will increase feasibility of biosimilar development (e.g., PD biomarkers, modeling and simulation)
f. Identify user interface differences that will likely lead to difference in use error rates or use success rates in the context of pharmacy substitution

Regulatory Impact to Achieve Demonstration Projects:

1. Increase reliance on analytical data in a demonstration of biosimilarity
2. Develop alternatives to and/or reduce the size of studies involving human subjects

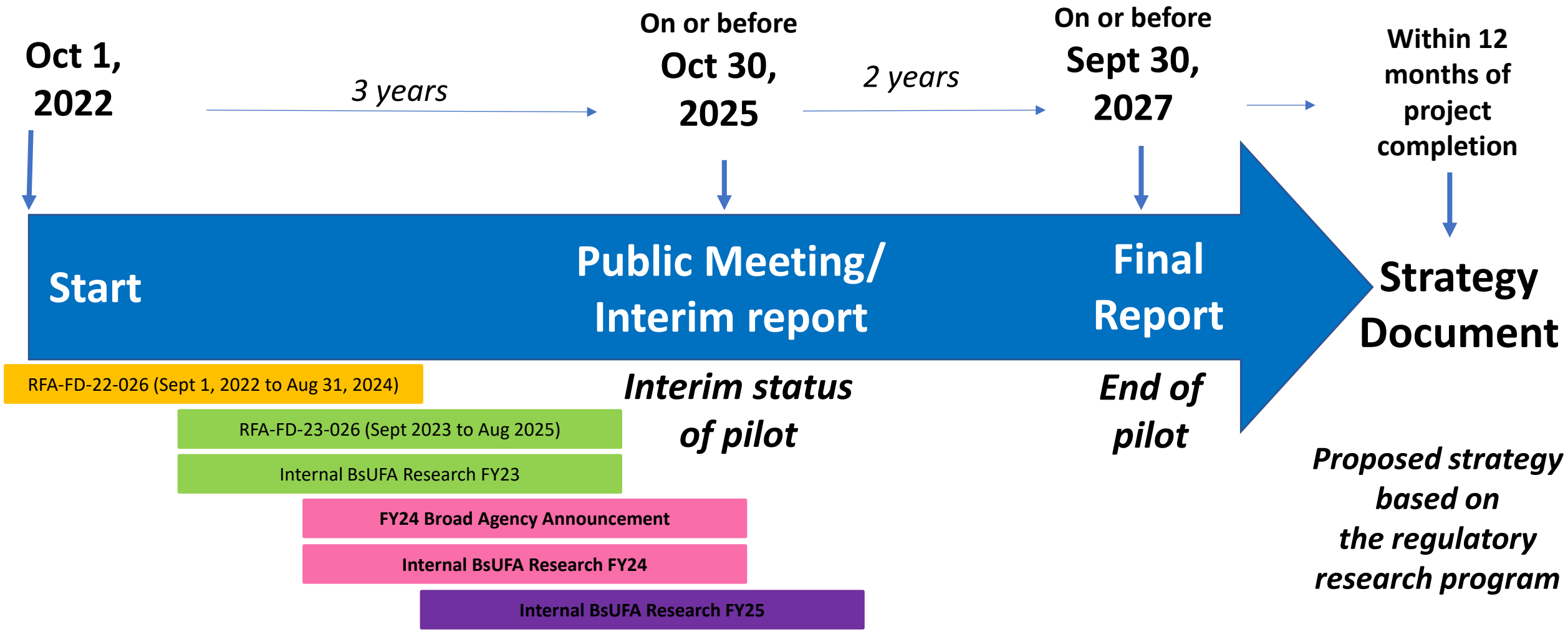
Demonstration Projects from BsUFA III

- Advancing the development of interchangeable products
- Improve the efficiency of biosimilar product development

Methods to consider for research conducted as part of the pilot program

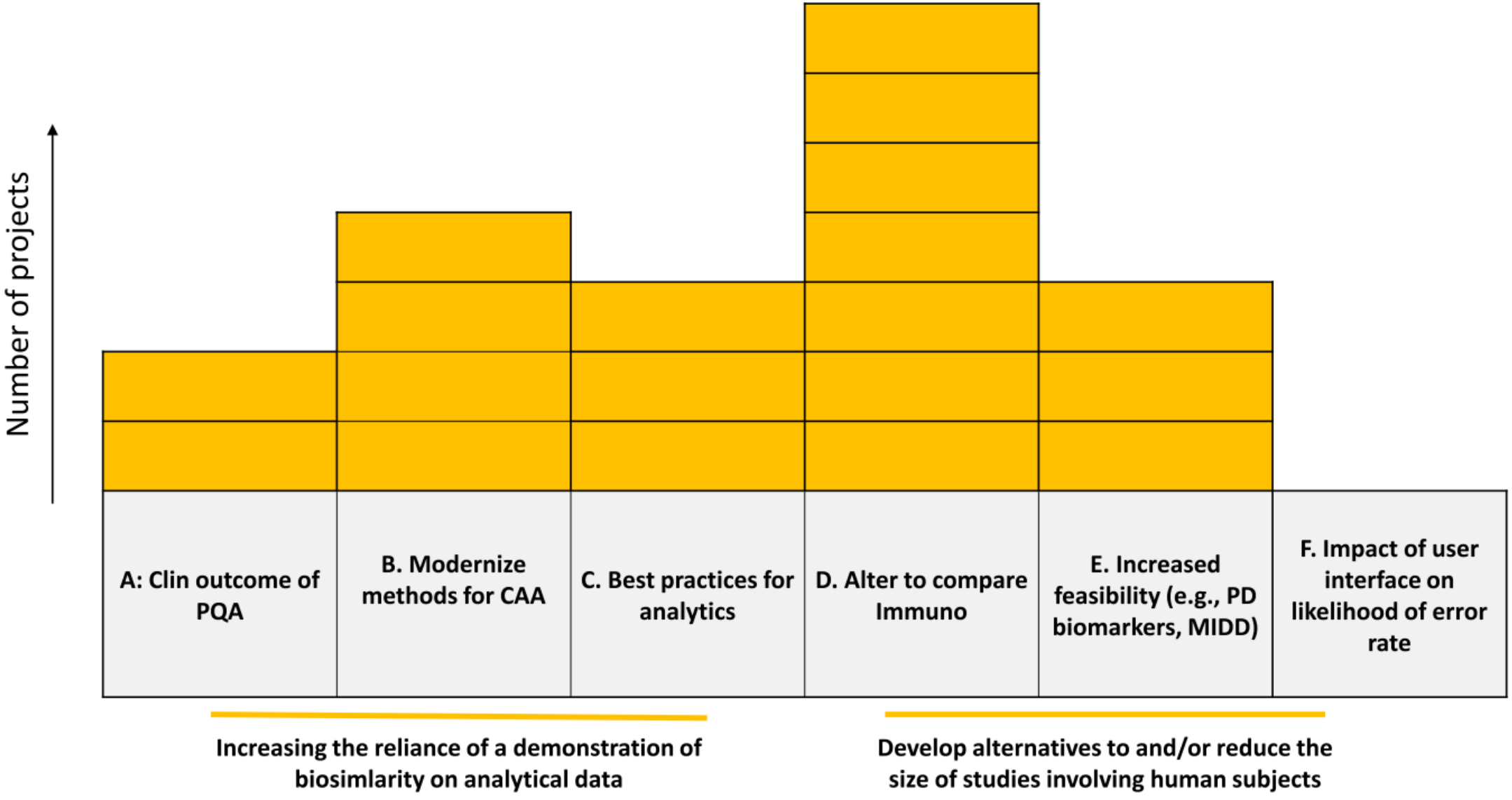
Analytical methods
Biological assays
Efficient clinical design (e.g., statistical methods)
In silico/in-vitro modeling
Model-informed drug development (MIDD) applications
Machine Learning/ Artificial Intelligence
Real World Evidence/ Data
Pharmacological studies

Pilot Program Completed Six Funding Cycles

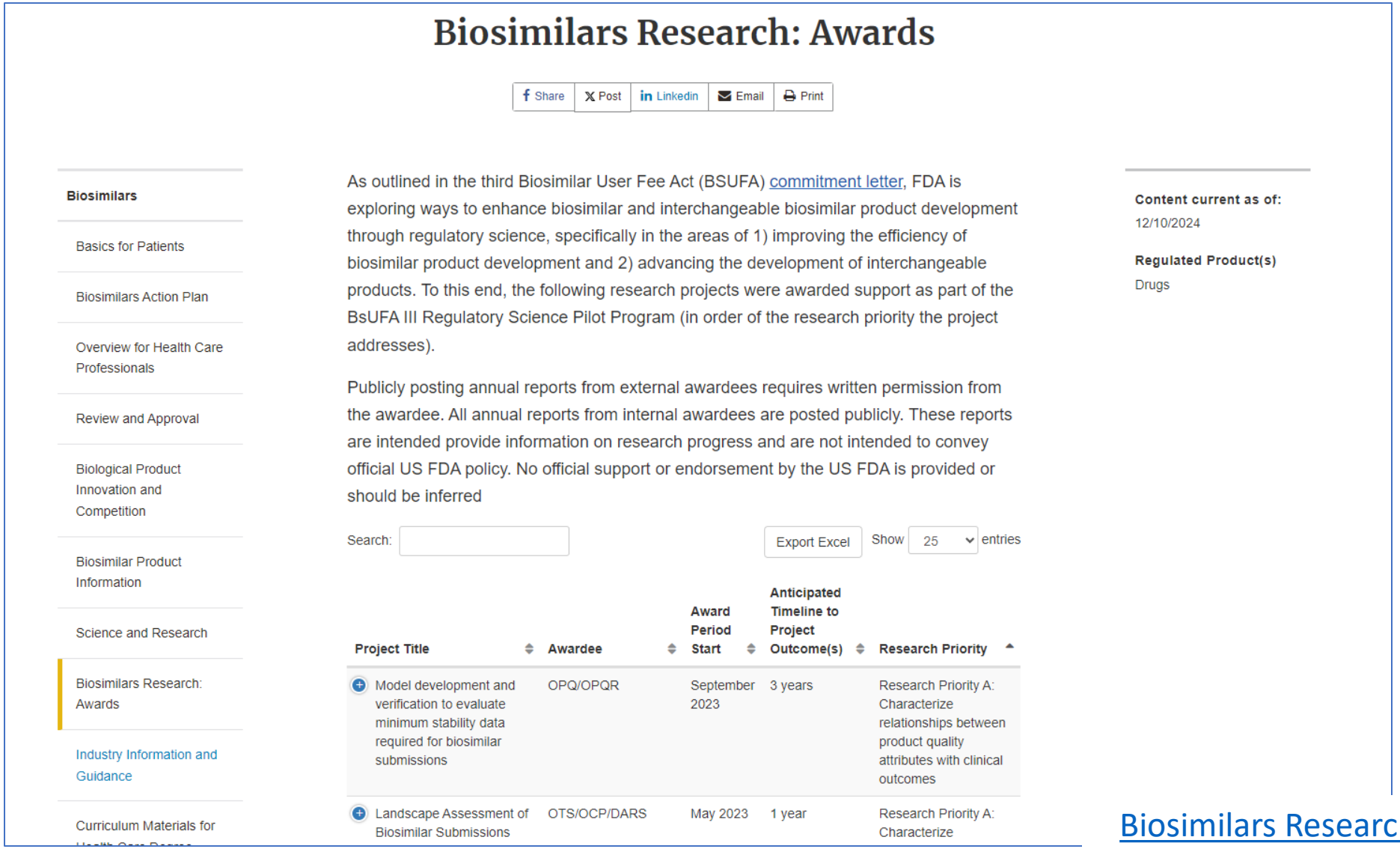


Research Priorities Addressed by Awarded Project (n=19)

as of Jan 2025



FY23 and 24 Research Annual Progress Reports Publicly Available



Biosimilars Research: Awards

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Biosimilars

- Basics for Patients
- Biosimilars Action Plan
- Overview for Health Care Professionals
- Review and Approval
- Biological Product Innovation and Competition
- Biosimilar Product Information
- Science and Research
- Biosimilars Research: Awards
- Industry Information and Guidance
- Curriculum Materials for

As outlined in the third Biosimilar User Fee Act (BSUFA) commitment letter, FDA is exploring ways to enhance biosimilar and interchangeable biosimilar product development through regulatory science, specifically in the areas of 1) improving the efficiency of biosimilar product development and 2) advancing the development of interchangeable products. To this end, the following research projects were awarded support as part of the BsUFA III Regulatory Science Pilot Program (in order of the research priority the project addresses).

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Content current as of:
12/10/2024

Regulated Product(s)
Drugs

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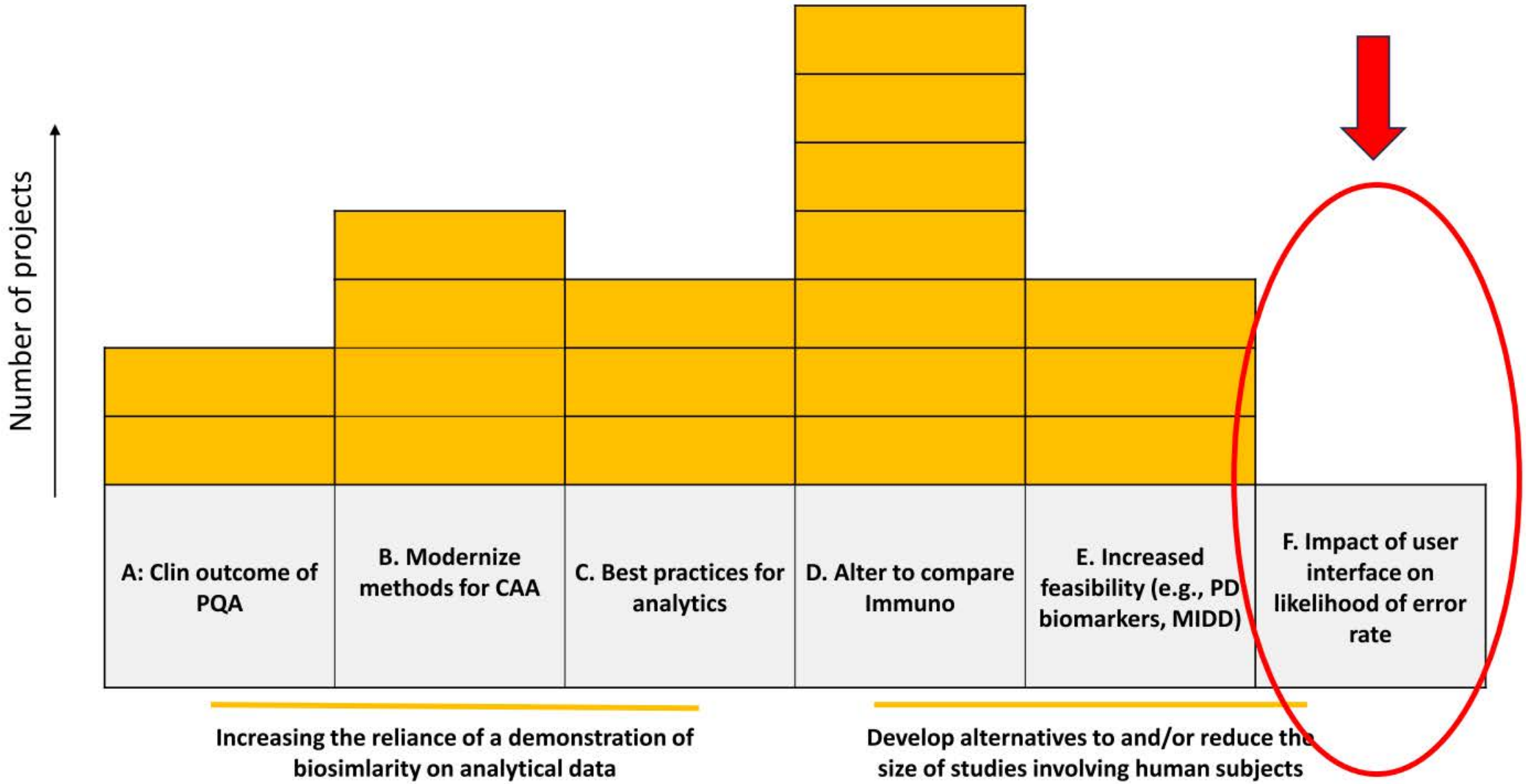
Project Title	Awardee	Award Period Start	Anticipated Timeline to Project Outcome(s)	Research Priority
Model development and verification to evaluate minimum stability data required for biosimilar submissions	OPQ/OPQR	September 2023	3 years	Research Priority A: Characterize relationships between product quality attributes with clinical outcomes
Landscape Assessment of Biosimilar Submissions	OTS/OCP/DARS	May 2023	1 year	Research Priority A: Characterize

[Biosimilars Research: Awards | FDA]

Funding Priorities for the Ongoing Funding Cycles



FY25 Broad Agency Announcement Closes February 24, 2025

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a. Identify user interface differences that will likely lead to clinically meaningful differences in use error rates or use success rates. For example, conducting a meta-analysis of the comparative use human factor studies (CUHF) - using any available data sets and/ or study reports from marketing applications to FDA - to inform whether differences in the activation steps of autoinjectors results in differences in success rate.

SAM.gov - FY25 BAA Announcement

Presentations of Awardees

Oct 2023 SBIA Webinar
Two *External* Awardee Presentations:

- **Dianne McCarthy from US Pharmacopeia**
  - **Priority B Project Title**: Assessment of the performance of MAM vs conventional Quality Control (QC) methods for evaluation of Product Quality Attributes of adalimumab and etanercept
- **Cate Lockhart, Academy of Managed Care Pharmacy, Inc.**
  - **Priority D Project Title**: Improving the Efficiency of Regulatory Decisions for Biosimilars and Interchangeable Biosimilars by Leveraging Real-World Data

Jan 2025 SBIA Webinar
Two *Internal* Awardee Presentations:

- **Jeffry Florian from Office of Clinical Pharmacology**
  - **Priority A Project Title**: Landscape assessment of biosimilar submissions
- **Kristina Howard from Office of Clinical Pharmacology**
  - **Priority D Project Titles**:
    - Addressing fundamental issues for in vitro immunogenicity testing
    - Validation of a non-clinical immunogenicity model and Production & optimization of humanized mice

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Interim Public Meeting
September 2025

All Awardees Present
(Oral Presentation or Poster)

Thank you!