FDA Broad Agency Announcement FY25 BsUFA III Regulatory Science Pilot Program

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The State of Biosimilars at FDA

*Approvals and Programs

59
Approved Biosimilars to **17** Reference products

15
Interchangeable biosimilars

38
Currently Marketed to **10** different reference products

98
BS development programs for 55 reference products

***As of September 6, 2024**

As a result….

Biosimilars have been used in over 694 million days of patient therapy

Nearly 24 billion dollars in savings since 2015

https://accessiblemeds.org/resources/blog/2023-savings-report

BsUFA III Regulatory Science Commitment

FDA is committed to enhancing regulatory decision-making and facilitating science-based recommendations in areas foundational to biosimilar development.

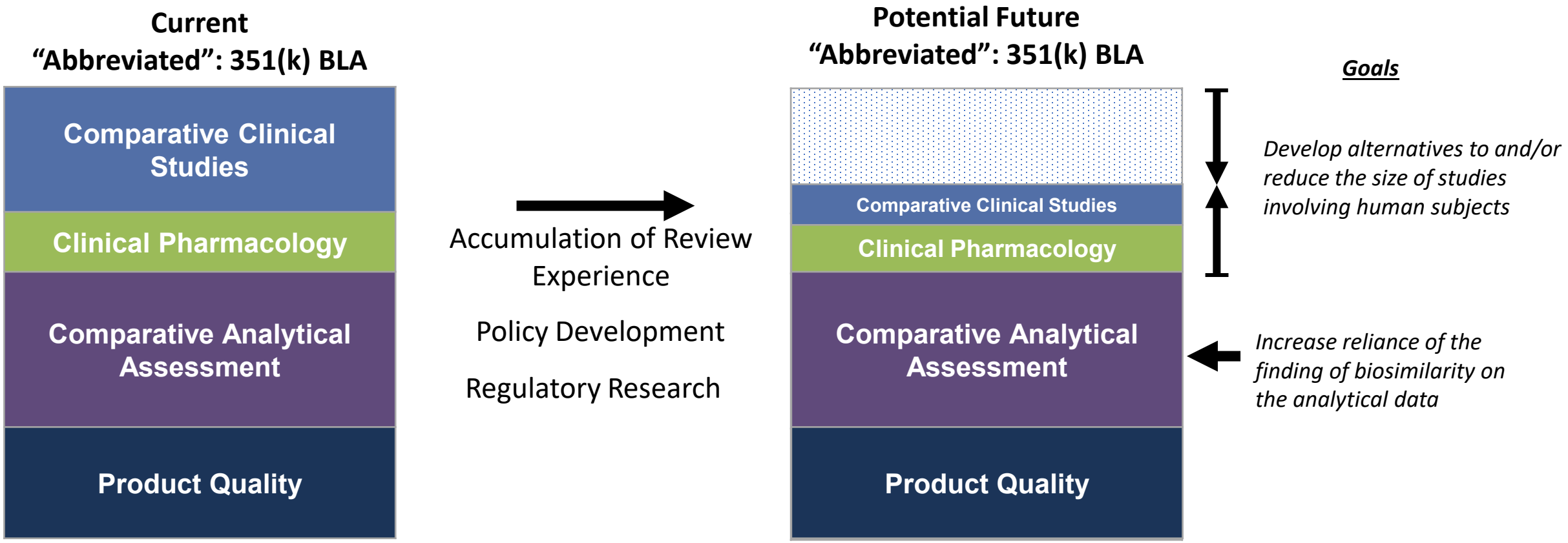
FDA will pilot a regulatory science program to facilitate ways to

(1) improve the efficiency of biosimilar product development and

(2) advance the development of interchangeable products

Commitment Letter

Regulatory Science Pilot Program Goals Focus on Composition of the 351 (k) Data Package



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Regulatory Impact #1: Increase the reliance on analytical data in demonstration of biosimlarity

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 quality attributes

Research Roadmap: *https://www.fda.gov/media/175799/download?attachment*

Regulatory Impact #2: Develop alternatives to and/ or reduce the size of studies involving human participants

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 clinically meaningful differences in use error rates or use success rates

Research Roadmap: *https://www.fda.gov/media/175799/download?attachment*

BAA Announcement FY25 - Biosimilars

BAA Priority Area	BAA Topic	Research Priority – BsUFA Reg Sci Roadmap
I. Modernize development and evaluation of FDA-regulated products	**A. Alternative Methods**	2. Develop alternatives to and/or reduce the size of studies involving human participants. i. Develop alternatives to the comparative clinical immunogenicity assessment(s) ii. Define approaches that will increase feasibility of biosimilar development (e.g., PD biomarkers, modeling and simulation). (pg. 11)
	C. Analytical & Computational Methods	1. Increase the reliance on analytical data in a demonstration of biosimilarity. i. Characterize relationships between product quality attributes (physiochemical or biological) with clinical performance ii. Explore how modernization of analytical technologies could better and/or more efficiently detect relevant quality attributes iii. Define best practices for assessing and reporting quality attributes 2. Develop alternatives to and/or reduce the size of studies involving human participants i. Develop alternatives to the comparative clinical immunogenicity assessment(s) ii. Define approaches that will increase feasibility of biosimilar development (e.g., PD biomarkers, modeling and simulation). (pg. 15-16)
	H. Methods for Assessing Behavioral, Economic, or Human Factors	2. Develop alternatives to and/or reduce the size of studies involving human participants i. Identify user interface differences that will likely lead to clinically meaningful differences in use error rates or use success rates.(pg. 31)

Research Priorities Addressed by Awarded Project (n=19)

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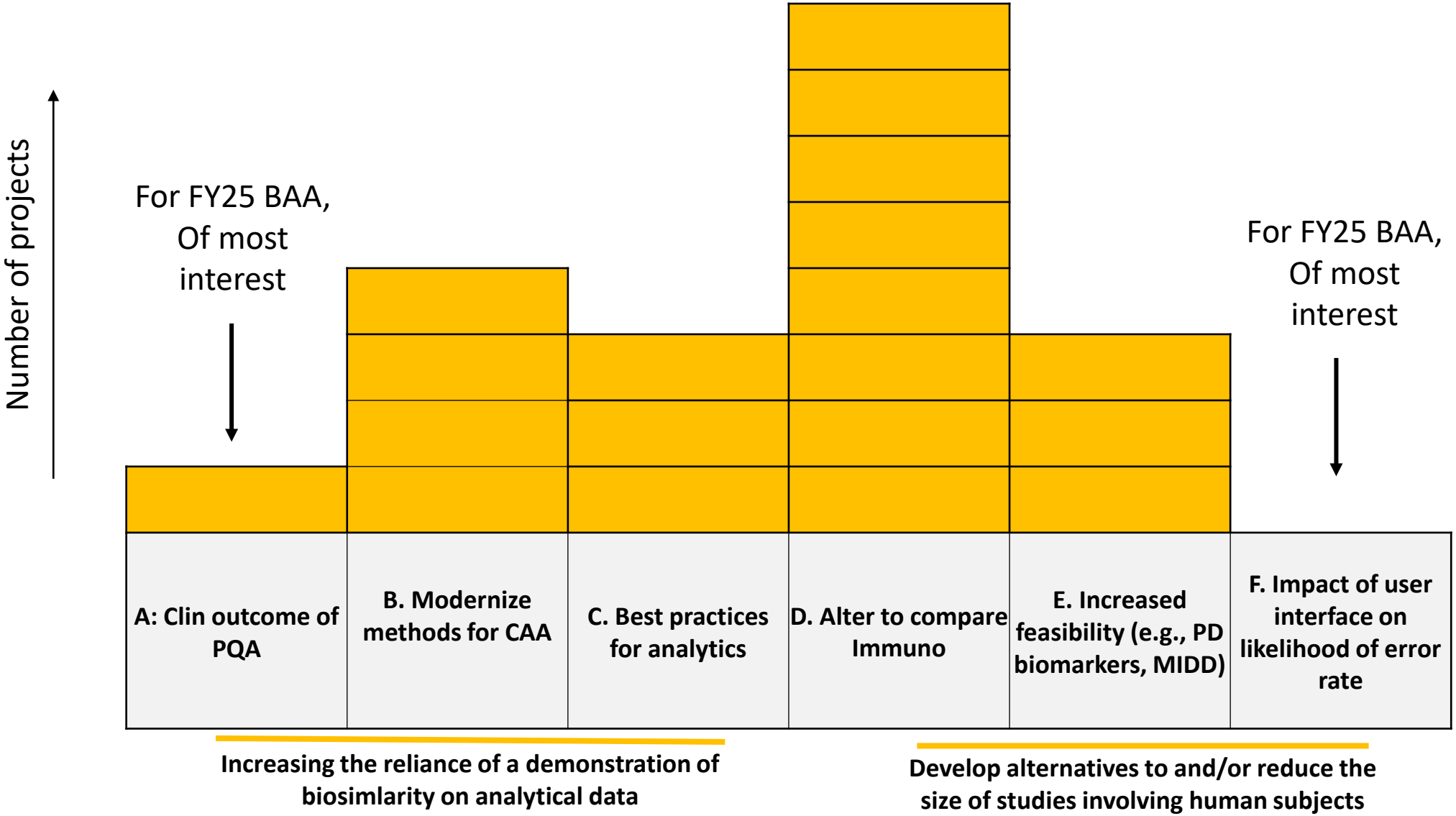

Additional Information

For information, please reach to:

- BsUFARegSciProgram@fda.hhs.gov

Additional Resources:

- Biosimilars | FDA
- Biosimilars | Science and Research | FDA
- BsUFA III Regulatory Science Pilot Program - 10/16/2023 | FDA
- Combined FY22-FY24 Regulatory Research Pilot Program Research Awards and Available Project Reports