FDA Broad Agency Announcement FY24 BsUFA III Regulatory Science Pilot Program

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BAA Day Oct 25, 2023

The State of Biosimilars at FDA

As of **October 5, 2023**:

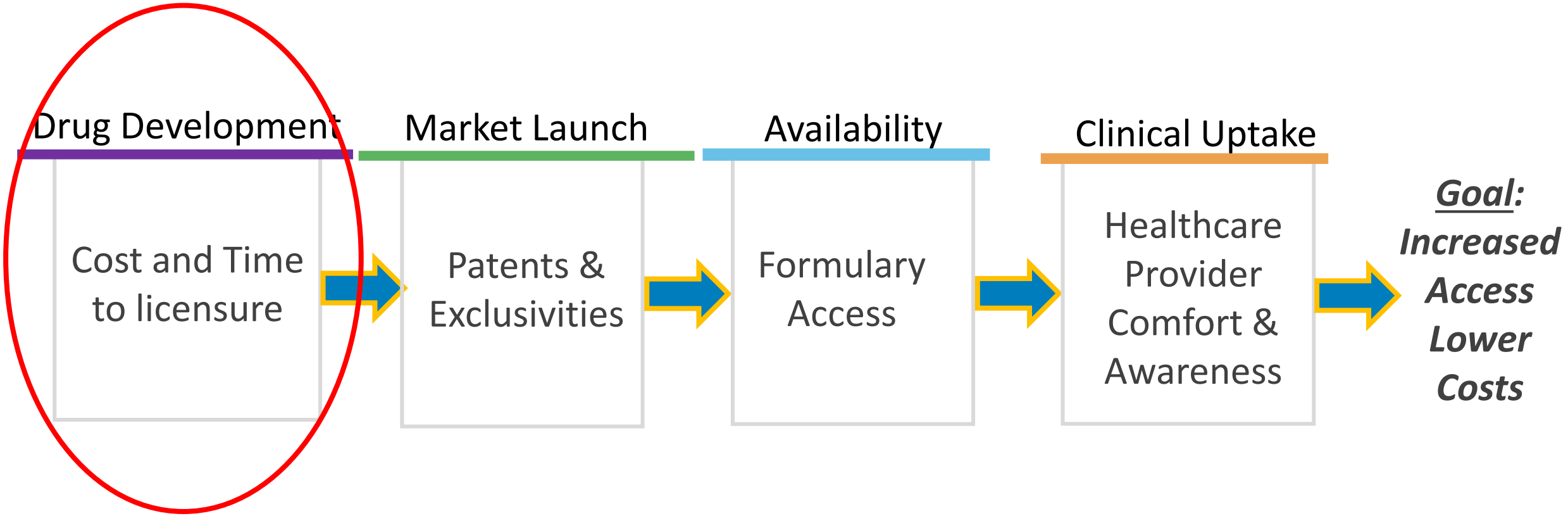
- CDER has received meeting requests to discuss the development of biosimilars for **54** different reference products

- FDA has approved **43** 351(k) BLAs for biosimilar products, **6** of which are interchangeable; **38** are marketed

Association for Accessible Medicines Report: 2023 U.S. Generic and Biosimilar Medicines Savings Report (September 2023)

Office of the Inspector General Report: Biosimilars Have Lowered Costs for Medicare Part B and Enrollees, but Opportunities for Substantial Spending Reductions Still Exist (September 2023)

Challenges and Barriers for Biosimilars in the U.S.



BsUFA III Enhancement Areas

Supplements | Introducing new supplement types and expedited review timelines

Meeting Management | Enhancing communication and feedback during the biosimilar biological development process

Best Practices| Implementing best practices in communication during application review

URRA and Human Factors Timelines | Introducing timelines for review of URRA and Human Factors studies

Inspections| Enhancing pre-licensure inspection communication and clarifying use of alternative tools

Interchangeable Products| Introducing focused effort to advance the development of interchangeable products

Regulatory Science | Introducing new pilot program to enhance regulatory decision-making and facilitate science-based recommendations

Finance | Enhancing financial management and transparency

Hiring and Retention | Focusing on the strategic hiring and retention of world-class technical and scientific staff

Information Technology| Investing in modern technology to support enhanced and streamlined biosimilar product development and review

BsUFA III Regulatory Science Commitment

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

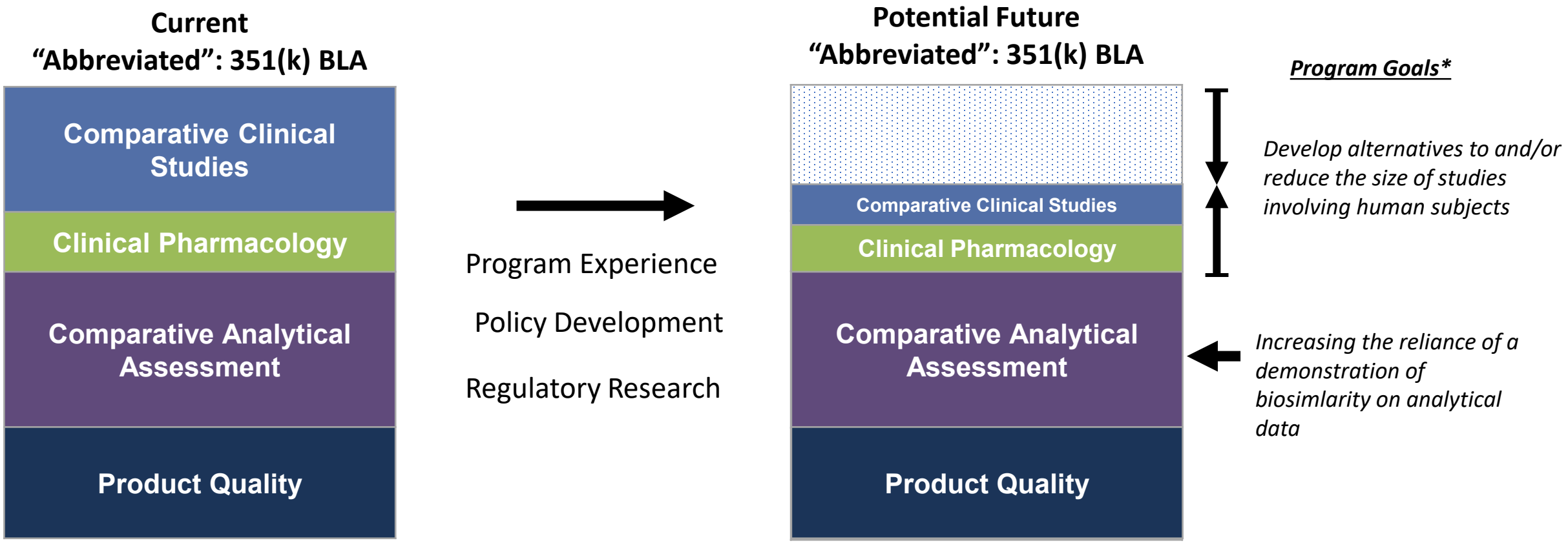
FDA will pilot a regulatory science program to facilitate ways to

(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



Research Roadmap under revision!

Regulatory Impact #1: Increasing the reliance of a demonstration of biosimlarity on analytical data*

a. Characterize relationships between product quality attributes (physiochemical or biological) with clinical outcomes

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 under revision!*

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

d. Develop alternatives to the comparative clinical immunogenicity assessment(s)

e. Define development approaches that will increase feasibility and/ or likelihood of successful biosimilar development

f. Identify user interface differences that will likely lead to differences in use error rates or use success rates in the context of pharmacy substitution

**Research Roadmap under revision!*

BAA Announcement FY24 - Biosimilars			Pilot Program Research Roadmap*
Priority Area	**Topic**	**Research Priority – BAA**	**Draft Research Priority – Roadmap**
I. Modernize development and evaluation of FDA-regulated products	**A. Alternative Methods**	Investigate and evaluate informative, scientifically appropriate methodologies to predict immunogenicity by advancing the knowledge of analytical (including physical, chemical, and biological function assays), pharmacological and clinical correlations as it relates to biosimilarity (pg.10)	d. Develop alternatives to the comparative clinical immunogenicity assessment(s)
	C. Analytical & Computational Methods	Review and evaluate opportunities for streamlining and targeting biosimilar product development in consideration of scientific advancements in analytical (including physical, chemical, and biological function assays), and pharmacological assessments and experience with prior biosimilar product development and marketed biosimilar products. (pg. 16)	a. Characterize relationships between product quality attributes (physiochemical or biological) with clinical outcomes b. Explore how modernization of analytical technologies could better and/or more efficiently detect relevant quality attributes e. Define development approaches that will increase feasibility and/ or likelihood of successful biosimilar development
	H. Methods for Assessing Behavioral, Economic, or Human Factors	Produce data that provides scientific clarity about (1) what user interface differences may affect the safe and effective use of the biosimilar interchangeable product as compared to the reference product when the biosimilar interchangeable product is substituted for the reference product, or (2) when the differences in the user interfaces between a proposed interchangeable product and a reference product should be further evaluated to determine if they affect safe and effective use of the biosimilar interchangeable product …[in the context of pharmacy substitution]…(pg. 33)	f. Identify user interface differences that will likely lead to differences in use error rates or use success rates in the context of pharmacy substitution
	J. Methods to Assess Real-World Data to serve as Real-World Evidence	Investigate and evaluate the data and information (including RWE) needed to meet the safety standards for determining interchangeability under section 351(k)(4) of the PHS Act. (pg. 36)	d. Develop alternatives to the comparative clinical immunogenicity assessment(s)

**Research Roadmap under revision!*

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