

# Program Introduction & Recap from Last Engagement



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# The State of Biosimilars at FDA

## Approvals and Programs

63

Approved  
Biosimilars to 17  
Reference products

16

Interchangeable  
biosimilars

41

Currently Marketed  
to 12 different  
reference products

112

BS development  
programs for  
58 reference  
products

**\*As of November 30, 2024**

*As a result..*



Biosimilar savings since 2015

**\$36 BILLION**



Biosimilars have been used in almost  
**2.7 BILLION DAYS** of patient therapy and  
have resulted in more than **495 MILLION  
INCREMENTAL DAYS** of therapy



Biosimilar competition is driving lower  
prices among biosimilars and their  
reference products

\*Source AAM / 2024 U.S. Generic and Biosimilar Medicines Savings Report  
<https://accessiblemeds.org/resources/blog/2024-savings-report>

# BsUFA III Regulatory Science Commitment

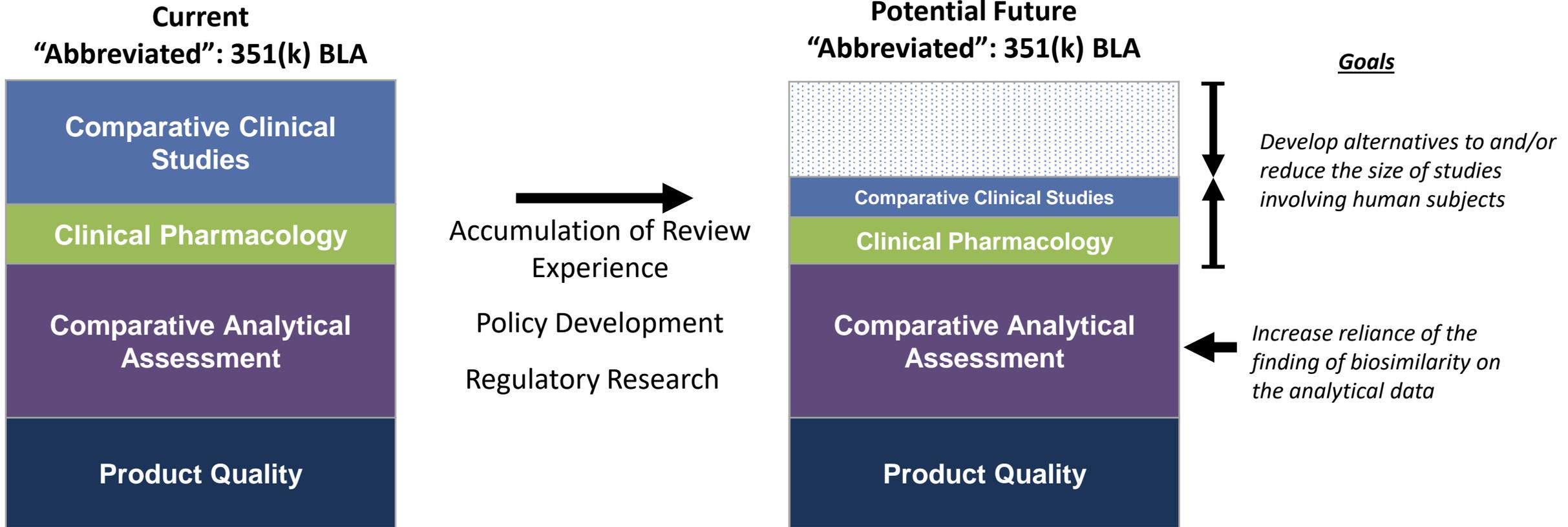
FDA is committed to enhancing regulatory decision-making and facilitating science-based recommendations in areas foundational to biosimilar development.

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



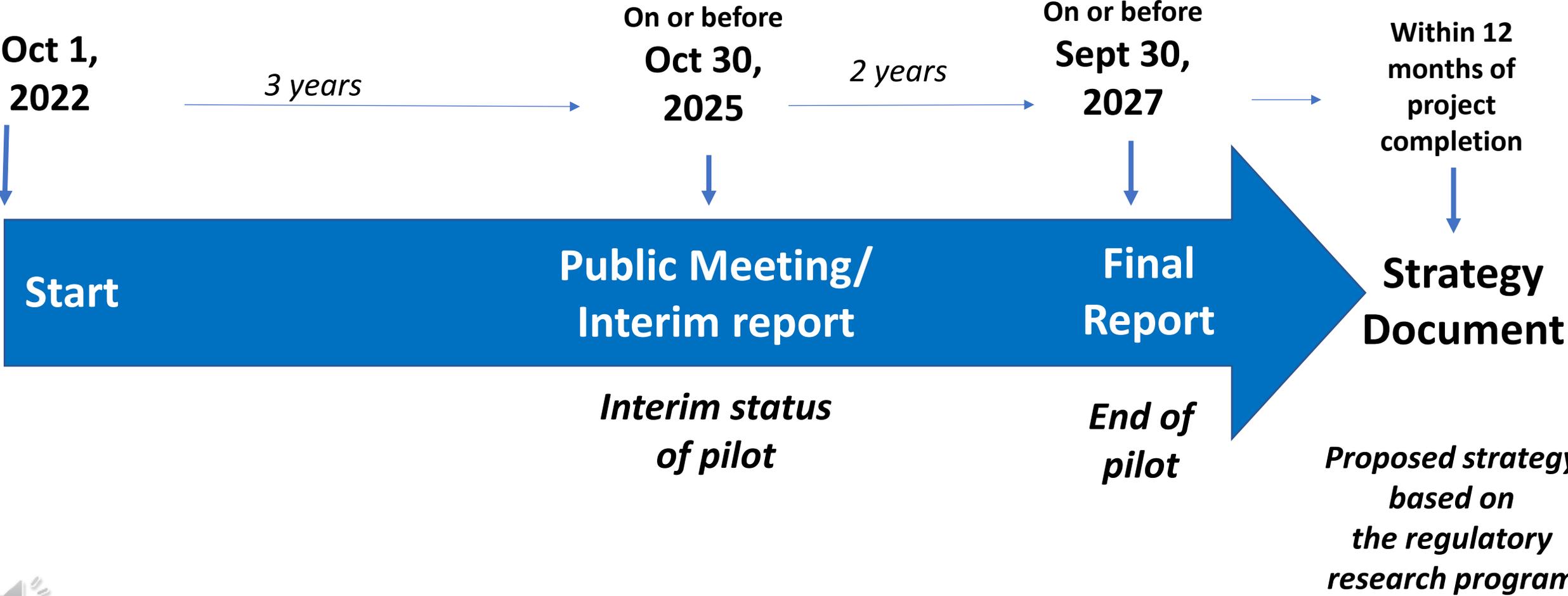
# Regulatory Impact #1: Increase the reliance on analytical data in demonstration of biosimilarity

- 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

## **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

# Regulatory Science Pilot Program Deliverables



# External Engagement and Communication on Pilot Program

## Eliciting Feedback on BsUFA III Research Roadmap

- **Public Comment Period on Draft Regulatory Roadmap (January 25 – April 5, 2023)**
- **Public SBIA meeting and in-person discussion Oct 2023- [BsUFA III Regulatory Science Pilot Program - 10/16/2023 | FDA](#)**

**\*Revised BsUFA III Research Roadmap Published in January 2024- [Revised BsUFA III Research Roadmap](#)**

## Other Types of Stakeholder Engagements

- **Continuous Engagement Meetings as part of BsUFA III-communication**
- **Eleven invited talks about the Reg Sci Pilot Program (Spring/ Summer/ Fall 2023/ Fall 2024)**
- **Published annual reports for entire research portfolio December 2024- [Biosimilars | Science and Research | FDA](#)**
- **Biosimilar Roundtables Conducted by Reagan Udall Foundation (RUF) (August –November 2024)- [Biosimilar Roundtables | Reagan-Udall Foundation](#)**

