

Program Introduction & Recap from Last Engagement



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Science Pilot Program | OPQAIH | OPQ | CDER | FDA



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 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

***As of November 30, 2024**

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

BsUFA III Regulatory Science Commitment

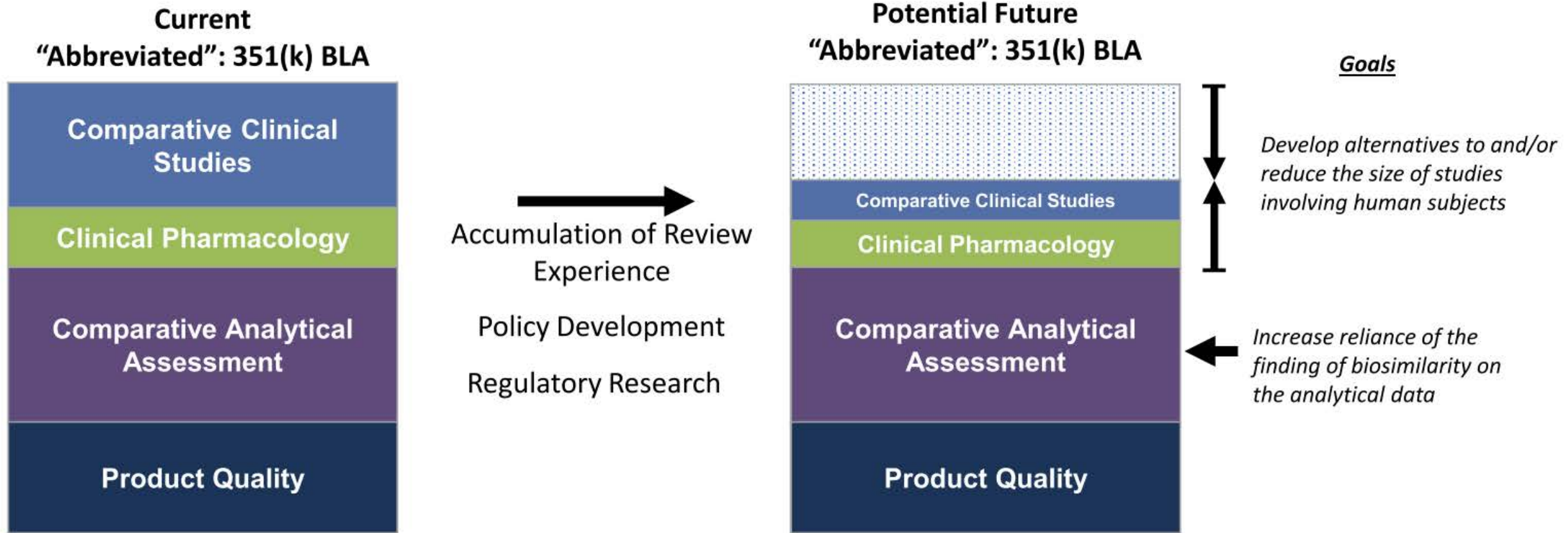
FDA is committed to enhancing regulatory decision-making and facilitating science-based recommendations in areas foundational to biosimilar development.

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



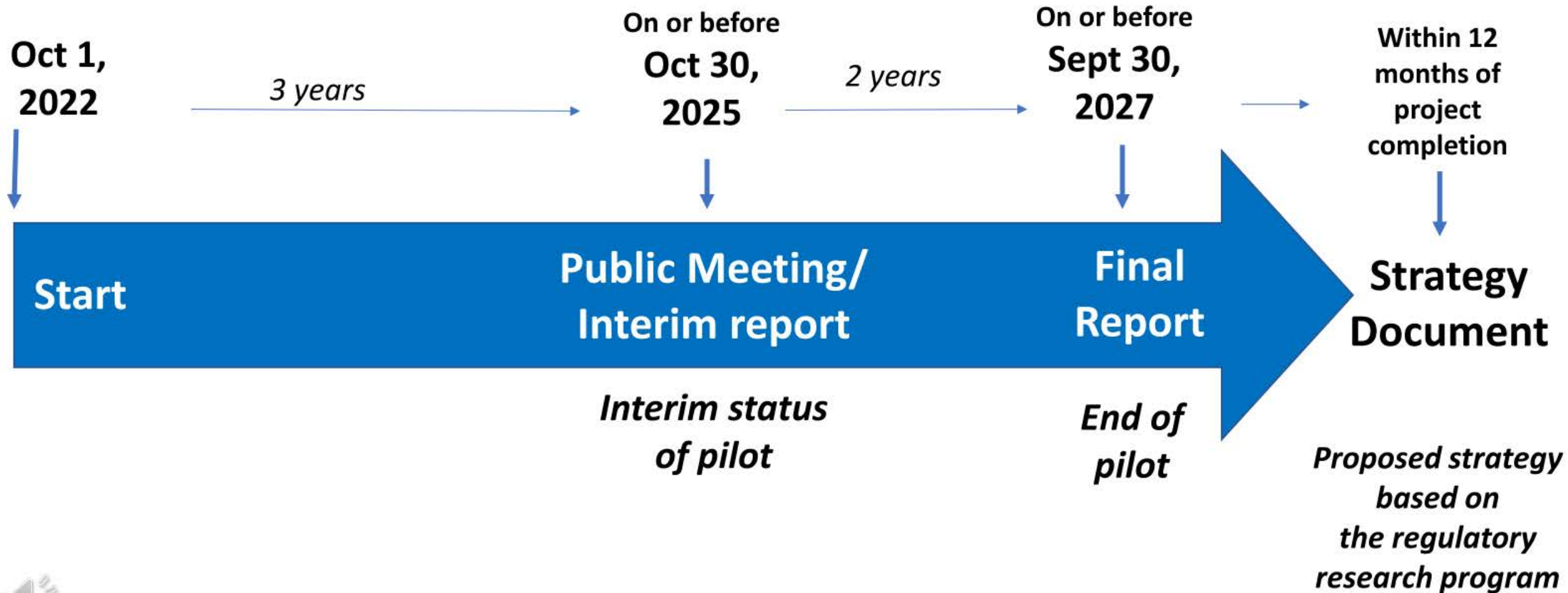
Regulatory Impact #1: Increase the reliance on analytical data in demonstration of biosimilarity

- 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*](#)

