Pilot Program Next Steps

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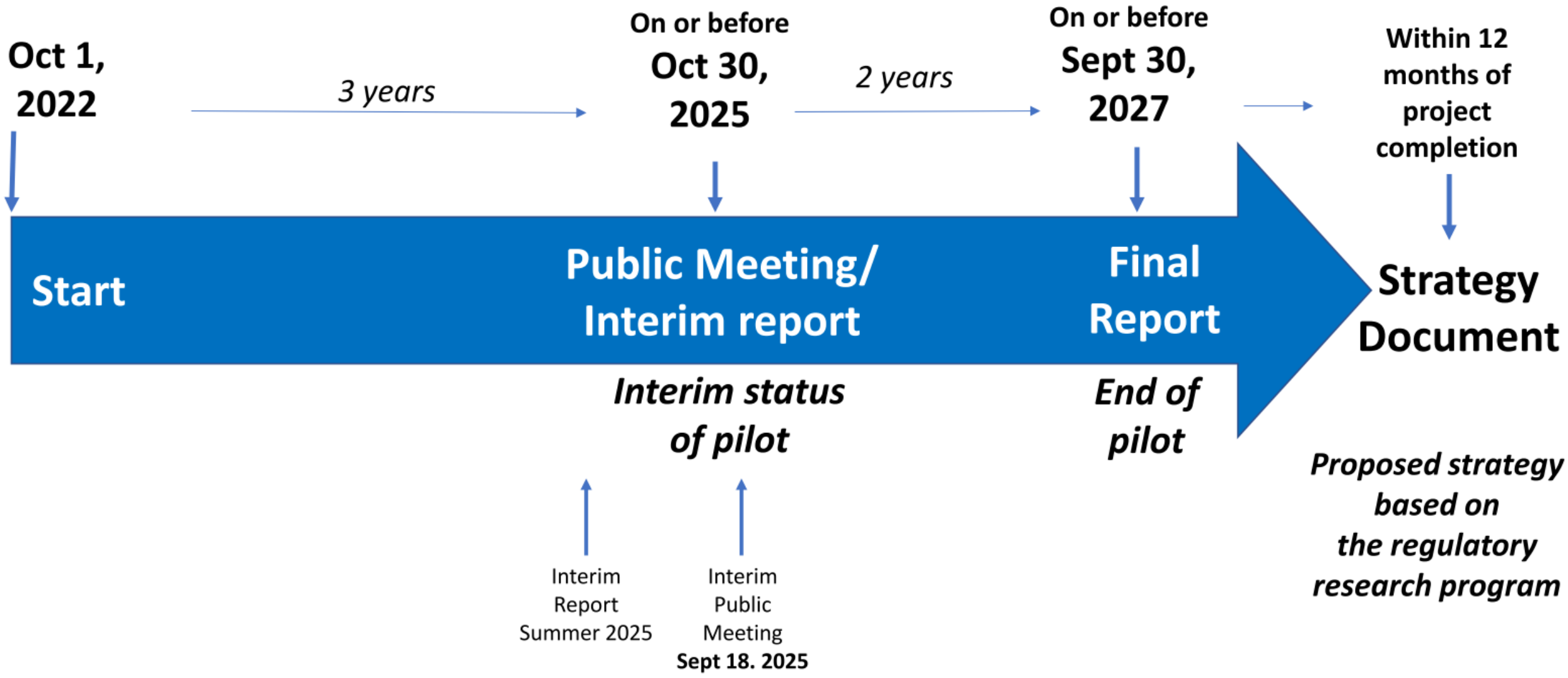
BsUFA III Regulatory Science Pilot Program

OTBB| OND| CDER| FDA

Interim Public Meeting *Planned for* September 18, 2025



Tentative Highlights for the Interim Public Meeting

- Development of and lessons learned standing up the Pilot Program
- Research Project Report Outs
- Discussion about the role of regulatory science in biosimilar development

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Which research projects do you want to hear more about at the Interim Public Meeting?

Audience Poll Questions

Poll Question 1

Which of the following research projects under ***research priority A*** would you like to hear more about at the Interim Public Meeting in September 2025?

A. **FDA/OTS** –“ Landscape assessment of biosimilar submissions (analytical, PK, PD, and comparative studies)”

B. **FDA/OND** –“ Assessment of Immunogenicity in Biosimilars a Systematic Review”

C. None of the above

Poll Question 2

Which of the following research projects under ***research priority B*** would you like to hear more about at the Interim Public Meeting in September 2025?

A. **USP-** "Assessment of the performance of MAM vs conventional QC methods for evaluation of Product Quality Attributes of adalimumab and etanercept"

B. **FDA/OPQ-** "Establishment of A Feasible Method to Quantify Major Glycoforms of Human IgG1 mAb Drugs and their Biosimilars in Culture Media as a Component of Process Analytic Technology"

C. **FDA/OPQ-** "OnePotGlycan - A chemoenzymatic method for simultaneous profiling of N and O-glycans in one-pot"

D. **FDA/OPQ-** "Model development and verification to evaluate minimum stability data required for biosimilar submissions"

E. None of the above

Poll Question 3

Which of the following research projects under ***research priority C*** would you like to hear more about at the Interim Public Meeting in September 2025?

A. **FDA/OPQ-** "Bioassay - Enhanced biosimilar testing capabilities"

B. **NIFTE-** "Platform for reliable characterization and evaluation of comparability of biosimilar drug products in lyophilized and liquid formulations"

C. **University of Michigan –"** Systematic Analytical Characterization of Innovator and Biosimilar Products with the Focus on Post-translational Modifications"

D. None of the above

Poll Question 4

Which of the following research projects under ***research priority D*** would you like to hear more about at the Interim Public Meeting in September 2025?

A. **AMCP-** "Improving the Efficiency of Regulatory Decisions for Biosimilars and Interchangeable Biosimilars by Leveraging Real-World Data"

B. **Epivax** -" ISPRI-HCP: CHO protein impurity immunogenicity risk prediction for improving biosimilar product development and assessing product interchangeability"

C. **AMPC-** "Bridging the Gap: Using Foreign Real-World Data to Inform Interchangeable Biosimilar Approvals"

D. **FDA/OTS** –"Validation of a non-clinical immunogenicity model"

E. **FDA/OPQ** –"IIRMI Assay Standards"

F. **FDA/OTS** –" Addressing fundamental issues for in vitro immunogenicity testing"

G. **FDA/OTS** – "Production & optimization of humanized mice"

H. None of the above

Poll Question 5

Which of the following research projects under ***research priority E*** would you like to hear more about at the Interim Public Meeting in September 2025?

A. **FDA/OTS** –"Translating Clinical Pharmacology Biosimilar [PD Biomarker] Research Findings into Best Practices for Industry and FDA Review Staff"

B. **FDA/OTS** –"Critical Factors for Standardization and Accuracy of PK Assays of PEGylated Biosimilars"

C. **FDA/OTS** –"Evidence-based approach to the design of clinical pharmacology studies"

D. None of the above