Biotechnology Innovation Organization

FDA Answers Your Questions About the STAR Pilot Program

February 15, 2024, 1:00 PM (ET)

Speakers:

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Overview of FDA Split Real Time Application Review (STAR) Pilot Program

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CDER | US FDA

FDA Answers your Questions about the STAR Pilot Program – February 15, 2024

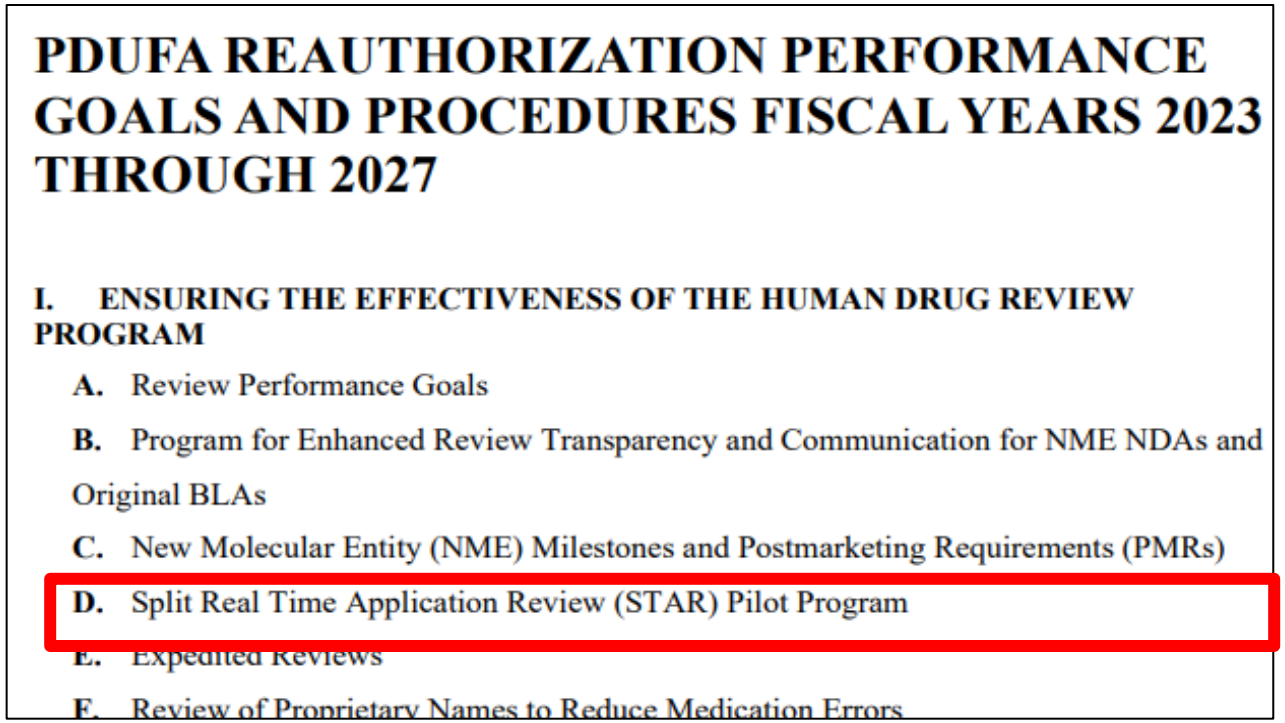
Learning Objectives

- Discuss the background of STAR pilot program
- Describe the STAR pilot program
- Outline CDER's review of STAR pilot program applications
- Discuss the STAR pilot program website
- Discuss STAR pilot program assessment
- List resources for Industry

Background

Prescription Drug User Fee Act (PDUFA):

- STAR introduced as a new pilot program under PDUFA VII
- Available to applicants beginning in FY 2023 (October 1, 2022)



PDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FISCAL YEARS 2023 THROUGH 2027

I. ENSURING THE EFFECTIVENESS OF THE HUMAN DRUG REVIEW PROGRAM

A. Review Performance Goals

B. Program for Enhanced Review Transparency and Communication for NME NDAs and Original BLAs

C. New Molecular Entity (NME) Milestones and Postmarketing Requirements (PMRs)

D. Split Real Time Application Review (STAR) Pilot Program

E. Expedited Reviews

F. Review of Proprietary Names to Reduce Medication Errors

Website: https://www.fda.gov/media/151712/download

Why the new STAR pilot program?

During user fee negotiations, Industry signaled that generally, data sets and other application contents are ready in advance of the Clinical Study Report (CSR), Integrated Summary of Safety (ISS), and Integrated Summary of Effectiveness (ISE).

Waiting for the CSR, ISS, and ISE can delay NDA/BLA submission to FDA.

Allowing submission of all other parts of a supplemental marketing application to start FDA review in advance of CSR, ISS, and ISE availability may enable earlier access to treatment addressing an unmet medical need.

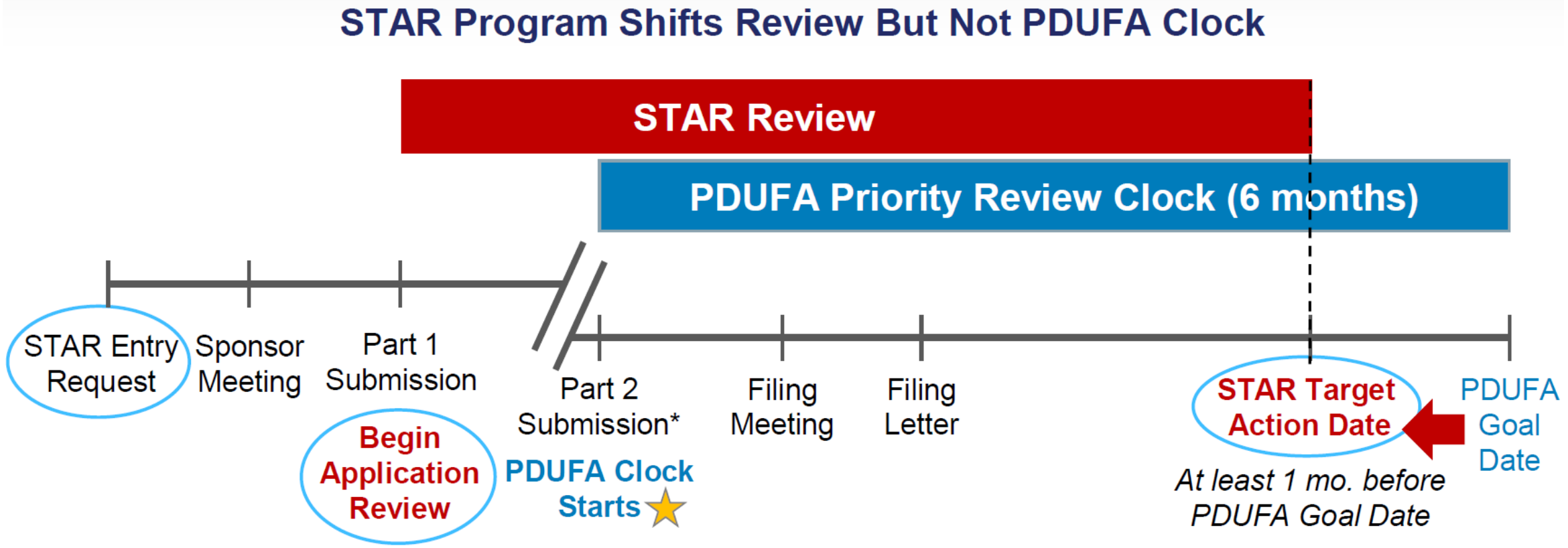
Goal of the STAR pilot program

To shorten the time from the date of complete supplement submission to the action date to allow earlier patient access to therapies that address an unmet medical need.

What is the STAR pilot program?

- A pilot program for qualified priority efficacy supplements
- Submitted in two parts to enable an earlier review and action

STAR Pilot Program Overview



*The **Part 2** Submission is usually received ~2 months after Part 1, but no more than 3 months after Part 1.

STAR Pilot Program Entry Request: Format

Option 1: Request as stand-alone T-con (no discussion of supplement content/format)

or

Option 2: Request as Part of a Type B pre-sNDA/sBLA meeting (to also discuss supplement content/format)

STAR Pilot Program Entry Request: Content

- Topline results from adequate and well-controlled clinical trials
- Proposed labeling
- Explanation of how the supplemental application meets STAR pilot program criteria

STAR Pilot Program Eligibility Criteria

1. Clinical evidence from adequate and well-controlled investigation(s) indicates that the drug may demonstrate substantial improvement on a clinically relevant endpoint(s) over available therapies
2. Application is for a drug intended to treat a serious condition with an unmet medical need

STAR Pilot Program Eligibility Criteria (continued)

3. No aspect of the submission is likely to require a longer review time
4. No chemistry, manufacturing, or control (CMC) information that would require a foreign manufacturing site inspection

STAR Pilot Program Split Submission: Part 1

Contains **all** elements of the supplemental application **except**:

- Clinical study report (CSR)
- Integrated summary of effectiveness (ISE)
- Integrated summary of safety (ISS)

STAR Pilot Program Split Submission: Part 1 (continued)

Part 1 submission should also include:

- Tables, Figures, and Listings
- Protocol and amendment(s) for pivotal trial(s)
- Statistical analysis plan and statistical analysis program for pivotal trial(s)
- Sponsor's high-level assessment summary of the safety and efficacy results
- Death summaries

STAR Pilot Program Split Submission: Part 1 (continued)

- If FDA identifies substantive **missing information**, reviews will stop
- A *Revocation of STAR Status* letter may be issued

STAR Pilot Program Split Submission: Part 2

- **Contains:** CSR, ISE, ISS
- **Timeline**:
  - PDUFA clock starts with Part 2 submission
  - Must be received by FDA no later than 3 months after Part 1 submission

STAR Pilot Program Split Submission: Part 2 (continued)

- If FDA identifies substantive **missing information**, reviews will stop
- A *Revocation of STAR Status* letter may be issued
- A *Refuse to File (RTF)* letter may be issued

STAR Pilot Program
Review Timeline Summary

- Review begins with the receipt of Part 1 submission
- PDUFA clock starts with receipt of Part 2 submission
- FDA will generally target an “expedited review”, meaning an action at least 1 month before the PDUFA goal date

STAR Pilot Program Resources

Split Real Time Application Review (STAR)

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Development Resources

- Advancing Real-World Evidence Program
- Antibacterial Drug Development Task Force
- BEST Resource Taxonomy
- Clinical Outcome Assessment Compendium
- Complex Innovative Trial Design Meeting Program
- Division of Pediatric and Maternal Health
- FDA-Recognized Antimicrobial Susceptibility Test Interpretive Criteria

Under the Prescription Drug User Fee Act (PDUFA) VII Commitment Letter[1], FDA is creating the Split Real Time Application Review (STAR) pilot program.

Overview

FDA is establishing a STAR pilot program, which aims to shorten the time from the date of complete submission to the action date, in order to allow earlier patient access to therapies that address an unmet medical need. The STAR pilot program will apply to efficacy supplements across all therapeutic areas and review disciplines that meet specific criteria. Accepted STAR applications will be submitted in a "split" fashion, specifically in two parts with the components submitted approximately two months apart.

FDA will begin to review the data once the agency receives the complete Part 1 Submission. The PDUFA review clock will start once the agency receives the Part 2 Submission, which will include the final clinical study report(s), the Integrated Summary of Safety, and Integrated Summary of Effectiveness. The program applies to both drugs and biologics, collectively referred to as drug(s). STAR is available for certain supplemental new drug applications (sNDAs) and supplemental biologics license applications (sBLAs) that propose new uses of approved therapies to address an unmet medical need. The program is available across all therapeutic areas.

STAR Eligibility Criteria

Content current as of:
02/17/2023

Regulated Product(s)
Drugs

Law(s) & Regulation(s)
Prescription Drug User Fee Act of 1992

www.fda.gov Website: https://www.fda.gov/drugs/development-resources/split-real-time-application-review-star

STAR Pilot Program Assessment

- FDA will conduct an interim assessment by the end of FY 2025
- FDA will also conduct a public workshop by the end of Q2 in FY 2026
- Outputs from the assessment and workshop will be published in a publicly available report

Frequently Asked Questions

Question 1: *When does FDA begin their review of a STAR application?*

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Response to Question 1:

Upon receipt of the STAR Part 1 submission

Frequently Asked Questions

Question 2: *When does the PDUFA clock start for a STAR application?*

Frequently Asked Questions

Question 2: *When does the PDUFA clock start for a STAR application?*

Response to Question 2:

Upon receipt of the STAR Part 2 submission

Frequently Asked Questions

Question 3: *When is the Integrated Summary of Safety submitted?*

Frequently Asked Questions

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Response to Question 3:

With the Part 2 Submission

Frequently Asked Questions

Question 4: *What is the difference between STAR and the Real Time Oncology Review (RTOR)?*

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Response to Question 4:

STAR is a PDUFA program open to development programs from any therapeutic area. RTOR is not a PDUFA program and is only available for oncology drug products.

Frequently Asked Questions

Question 5: *Does the STAR pilot program apply to oncology products, or should the sponsors of those products apply only to RTOR?*

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Response to Question 5:

Both STAR and RTOR are available to oncology products. However, sponsors should discuss their preference with the RPM of the relevant oncology division, for their particular product, to receive further guidance.

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Question 6: *What happens if an applicant does not submit the Part 2 submission within 3 months of the Part 1 submission?*

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Response to Question 6:

If Part 2 is not submitted within 3 months of Part 1, the application will be removed from the STAR pilot program.

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Response to Question 7:

Both programs utilize the same criteria for clinical evidence. A formal BTD granted is not required for STAR entry.

BTD primarily provides benefits during the drug development or IND.

STAR is intended to provide benefit during the review of the supplemental marketing application.

Frequently Asked Questions

Question 8: *Is STAR only applicable for supplementary NDAs or BLAs?*

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Response to Question 8:

Yes, currently STAR is only available for efficacy supplements which meet the STAR criteria.

Frequently Asked Questions

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Response to Question 9:

Supplemental applications that require an inspection of a foreign manufacturing site do not qualify for STAR.

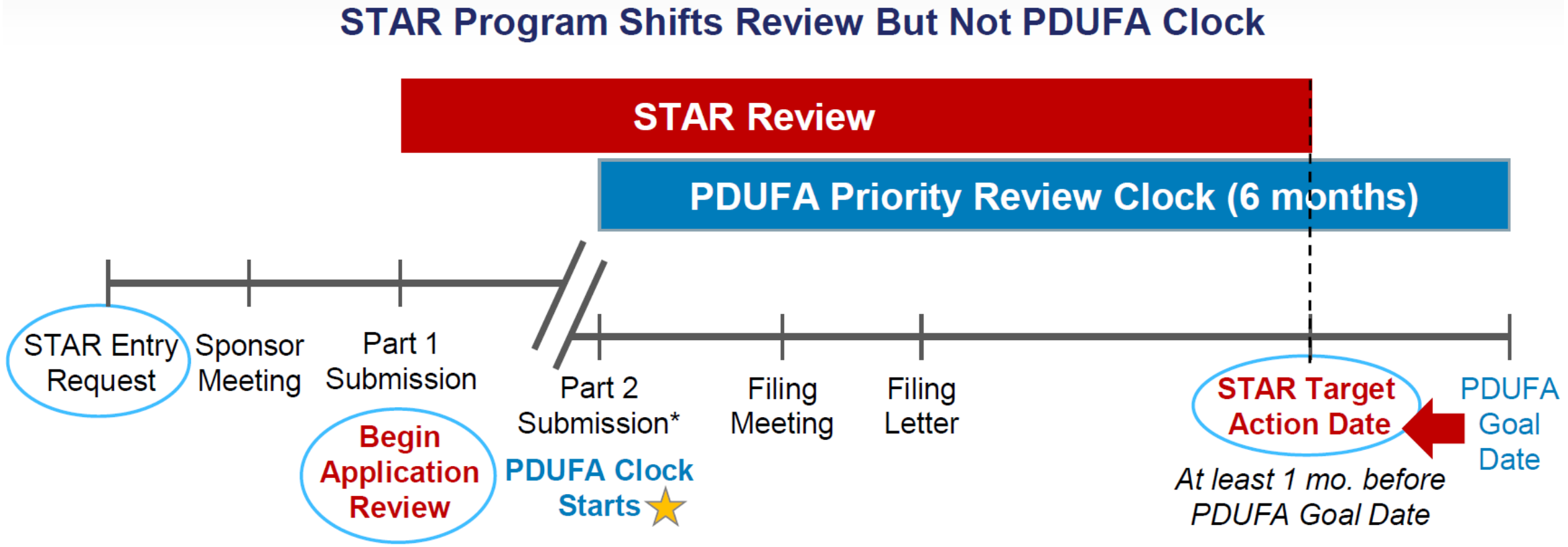
Resources

1. PDUFA VII Commitment Letter
2. FDA STAR Website

Summary

- The goal of the STAR pilot program is to shorten “the time from the date of complete submission to the action date, in order to allow earlier patient access to therapies that address an unmet medical need”
- A STAR application is submitted in two parts to enable FDA to start their review earlier and potentially take an earlier action
- The STAR pilot program is limited to Priority Efficacy Supplements that meet certain criteria

STAR Pilot Program Overview



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Questions?

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Closing Thought

Remember to include all components required for the Part 1 and Part 2 submissions in order to utilize the benefits of the STAR pilot program.


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