

The Commissioner's National Priority Voucher (CNPV) Pilot Program

CDER, CBER, OCE Town Hall
Pilot Program Overview

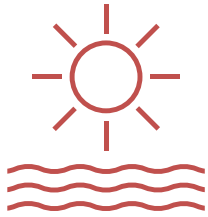
February 3, 2026

Office of the Chief Medical Officer
Office of the Commissioner



What is the CNPV Pilot Program?

An Ultra-Accelerated Priority Review Pilot Program (CDER, CBER, OCE)



Presubmission requirements



Target review clock: ~1-2 months



Aligned with National Priorities

Public Health Crisis

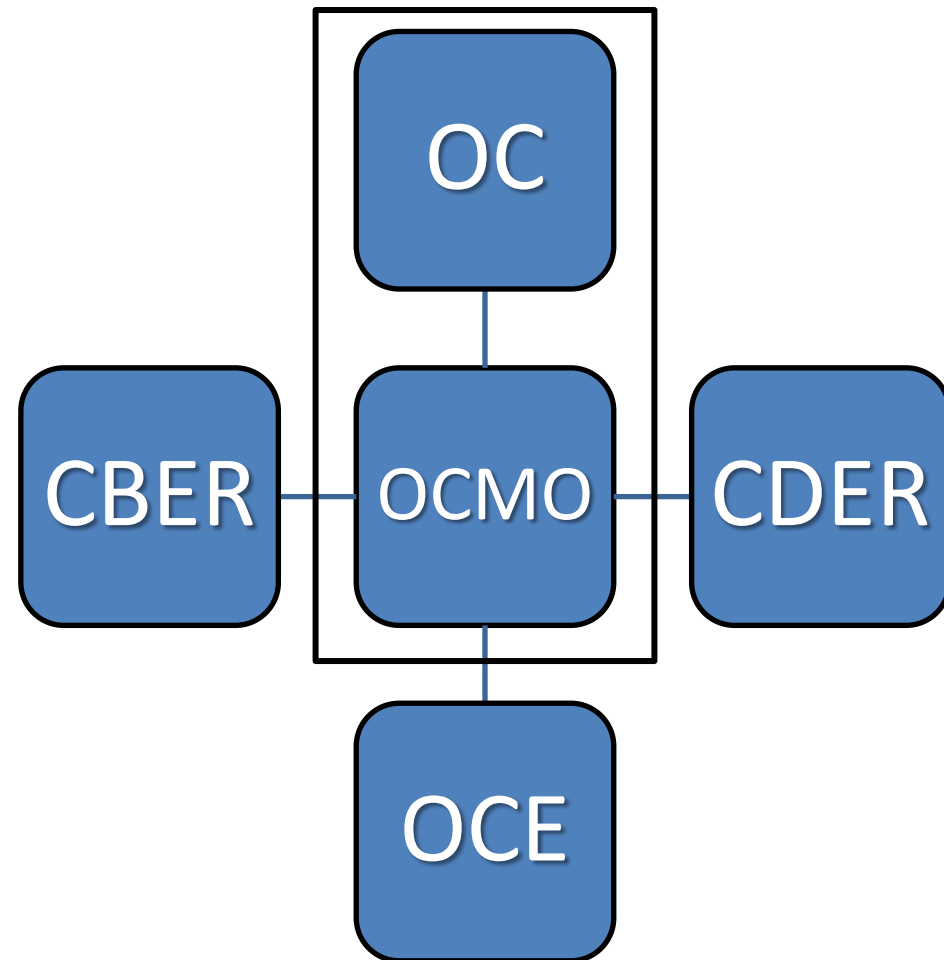
Innovative Cures

Large Unmet Need

Onshoring

Affordability

Our Role



Overview of CNPV Process



1. Select



2. Review



3. Recommend

How Are Voucher Selections Made?

1. Identify

- Nominations from internal stakeholders
- Online submissions from sponsors

2. Screen

- Iterative screening and vetting
- Alignment with priorities
- Operational considerations

3. Select

- Consensus-based — senior leadership, subject matter experts

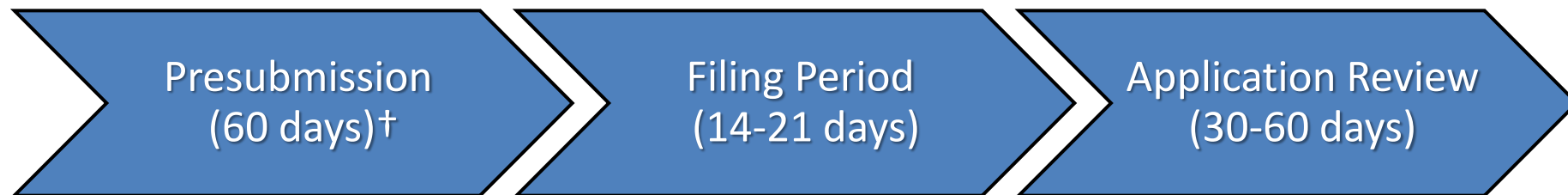
Nomination/Selection

NOMINATION and SELECTION \neq AUTOMATIC APPROVAL

NOMINATION and SELECTION =  SPEED OF DECISION

What Does the CNPV Review Process Look Like?

- Primary FDA review teams with the appropriate subject matter expertise remain responsible for the scientific review and developing an independent recommendation regarding the approval decision
- Review process includes flexibility: presubmission, filing period, and application review
 - More or less time may be appropriate for any period based on circumstances
- Structure builds on elements from RTOR program and STAR pilot*



* RTOR Program Overview (OCE): <https://www.fda.gov/about-fda/oncology-center-excellence/real-time-oncology-review>; Guidance for Industry: [Real-Time Oncology Review \(RTOR\) | FDA](#); [Split Real Time Application Review \(STAR\) | FDA](#)

† May be longer if foreign inspections required

Who Are the Members of the CNPV Review Council?

- Also previously referred to as the “tumor board style panel,” the CNPV Review Council is made up of the following standing and ad hoc members:
 - Non-voting, convenor
 - FDA Commissioner
 - Voting, standing members
 - Principal Deputy Commissioner
 - Center Directors
 - Deputy Center Directors*
 - Chief Medical and Scientific Officer
 - Deputy Chief Medical Officer
 - Senior advisors
 - Voting, ad-hoc members
 - Office leadership or other review division nominees to represent reviewer expertise
 - Other specific subject matter expertise as deemed important by the reviewing team (e.g., biostatistics)

*may attend in addition to or in place of the Center Director at the Center Director’s discretion

What Happens During a CNPV Review Council Meeting?

- The primary review team will present to the Council and provide their **preliminary scientific recommendation** and supporting rationale on relevant portions of the application
- The Council will provide a **non-binding scientific recommendation** determined by vote using pre-specified voting questions
- The Center Director will consider the preliminary recommendation of the primary review team and the Council and will convey a **non-binding scientific recommendation** to the review team

Voting question:

“How would you characterize the overall benefit-risk profile based on the information presented?”

(Options: Favorable, Uncertain, Unfavorable, Unable to Determine)

Who Makes the Final Approval Decision?

- The Council and Center Director make non-binding recommendations on parts of an application
- The approval decision remains with the relevant product Center, using the Center's normal processes:
 - All authority is delegated from the Commissioner to the Center directors and further delegated to appropriate offices or divisions
 - The goal is for the review team (specifically, the office director or division director, as appropriate) to serve as final signatory, though the management chain may override pursuant to existing procedures
 - The program looks to principles of equal voice
 - Additional discussion may be pursued with the objective of seeking alignment
 - Additional subject matter experts may be engaged

Immediate Next Steps

- Evaluate and integrate Center feedback regarding draft SOPP
- Meet with CNPV Pilot Advisory Group to discuss implementation of the program and necessary refinements to program
- Share additional information with external stakeholders, request feedback
 - Update externally facing website
 - Issue FRN to request public feedback
 - Host listening session(s) for external groups
 - Develop and share draft Guidance regarding program

A Commitment to Continuous Improvement

Plan, Do, Check, Act

