FY2026 Office of Infectious Diseases Funding Announcement to Facilitate Development of Susceptibility Test Interpretive Criteria (STIC or Breakpoints) for *Candida auris* through the FDA Broad Agency Announcement

The FDA Broad Agency Announcement (FDABAA-26-00123) is an open solicitation for research and development to support regulatory science and innovation. The FY26 FDA BAA solicitation, including detailed information regarding proposal preparation and submission, can be viewed here: https://sam.gov/workspace/contract/opp/5622acb8db634d37b3b55d607e6ba561/view

In fiscal year 2026, the following research area has been identified as a priority area by the Office of Infectious Diseases in FDA's Center for Drug Evaluation and Research.

- Charge Area: III. Invigorate public health preparedness and response of the FDA, patients, and consumers.
- Regulatory Science Topic of Interest: B. Antimicrobial Resistance
- FDA-Regulated Areas: 1. Drugs
    - **1a - Advance the science of antimicrobial drug susceptibility testing to ensure that up to date susceptibility testing interpretive criteria (breakpoints) are available for patient care and antimicrobial stewardship.**

Specifically, research proposals focused on evaluating microbiologic and pharmacokinetic data that could be utilized by standards development organizations and the FDA to update susceptibility test interpretive criteria (breakpoints) will be prioritized.

Depending on scientific merit of Full Proposals, the Agency anticipates awarding one research contract to address charge area IIIb1a. The total funding for this priority area will not exceed **$375,000** (direct and indirect cost).

Background

Appropriate selection of antimicrobial drugs is critical to individual patient care and public health. The selection of an appropriate antimicrobial drug is guided by breakpoints, the criteria to interpret antimicrobial susceptibility testing (AST) results. *Candida auris* (*C. auris*) is an important clinical pathogen that can cause life-threatening, often multi-drug-resistant infections. *C. auris* usually affects ill or immunocompromised patients and is highly transmissible in healthcare settings. Echinocandins are the initial recommended treatment of *C. auris* infections. The activity of azoles and other antifungal drugs against *C. auris* varies. Only rezafungin has a susceptible breakpoint against *C. auris* established by the Clinical Laboratory and Standards Institute; however, these breakpoints are not recognized by the FDA (Rezafungin Injection | FDA). While nonclinical (in vitro and in vivo) pharmacokinetic-pharmacodynamic (PK-PD) data are instrumental in establishing breakpoints, existing nonclinical models of *C. auris* infection are limited.

Research Proposal Objectives

FDA is interested in advancing the science of drug susceptibility testing in the treatment of *C. auris* infections. Research objectives specific to *C. auris* could include:

- Establishment of new or improvement of existing nonclinical models of *C. auris* infection.
- Establishment of relevant PK-PD parameters to inform PK-PD analyses of antifungal drugs.
- Defining nonclinical PK-PD cutoffs for antifungal drugs studied

Research Proposal Preparation Considerations

Concept Papers and Full Proposals will be evaluated based on program relevance to new drug development and regulatory review, overall scientific and technical merit, and offeror capability.

Offerors should provide relevant background to justify the proposed model and selected antifungal drugs.

The Full Proposal should include sufficient detail regarding planned microbiologic and pharmacokinetic studies and analyses. The research proposals could include:

- MIC distribution data for selected antifungal drugs against *C. auris* surveillance isolates collected in the preceding 3 years including isolates with various known resistance phenotypes and details on specific strains used in experiments, e.g., susceptibility and virulence factors (presence of known resistance genes).
- Nonclinical infection models to characterize PK-PD efficacy and emergence of resistance relationships, identify the PK-PD index, and select target values to be used to bridge this information to humans. Relevant information may include:
    - *In vivo* or *in vitro* PK-PD infection models including confirmatory assessments of growth of the selected strains under no treatment.
    - *In vivo* or *in vitro* infection model findings utilizing human-simulated antimicrobial exposures.
- Human pharmacokinetic data of the drugs in plasma.
- PK-PD modeling, Monte Carlo simulations, and probability of target attainment analyses.

Offerors should include a description of their qualifications, capabilities, related experience, and past performance, and describe their plan to make research findings publicly available for consideration by the FDA and standards development organizations. For example, FDA has opened a public docket for information and data relevant to updating breakpoints[1]. The contractor will also be responsible for subcontracting with institutions and other collaborators.

It is anticipated that research contract awards will be made through the FY26 FDA BAA.

Submission Deadlines:

- Stage I Package (Concept Paper and Full Proposal) – **February 24, 2026**

Office of Infectious Diseases Research Webpage:
https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-infectious-diseases-research-activities

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[1] https://www.regulations.gov/docket?D=FDA-2017-N-5925