FY2027 Office of Infectious Diseases Research Priority Area for
Molecular Surveillance of Antimicrobial Resistance in *Neisseria gonorrhoeae*

The FDA Broad Agency Announcement FDABAA-27-00123 is an open solicitation for research and development to support regulatory science and innovation. The FY27 FDA BAA solicitation, including detailed information regarding proposal preparation and submission, can be viewed here: FY27 BAA-Sam.gov.

In fiscal year 2027, 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.

- Areas of Regulatory Science: 5. Antimicrobial Resistance

    - *1. 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. For example, provide updated data from microbiologic surveillance studies, pharmacokinetic studies, including modeling, and/or clinical outcome data to support updating susceptibility test interpretive criteria for certain antimicrobial drugs that are a high public health priority.*

Specifically, research proposals focused on molecular surveillance of *Neisseria gonorrhoeae* for postmarket monitoring of antimicrobial resistance will be prioritized.

Depending on the scientific merit of Full Proposals, the Agency anticipates awarding one research contract to address regulatory science area 5 on antimicrobial resistance**.** Historically funding for this type of research has been made in the amount of $300,000 (direct and indirect costs).

Background

Postmarketing surveillance for antimicrobial resistance (AMR) is required under section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (FDCA), which authorizes the FDA to mandate studies to assess the emergence of resistance for 5 years following drug approval. AMR surveillance has traditionally relied on culture-based, phenotypic susceptibility testing methods (e.g., minimum inhibitory concentration [MIC] determination) to detect changes in pathogen susceptibility over time. However, the increasing availability of molecular diagnostic technologies has expanded the capacity to identify specific genetic resistance mechanisms. As a result, inclusion of genotypic AMR assessment into both surveillance and clinical practice is becoming more prevalent, complementing phenotypic approaches, and enabling more rapid and targeted detection of resistance mechanisms.

Drug-resistant *N. gonorrhoeae* has been designated by the Centers for Disease Control and Prevention (CDC) as an urgent antimicrobial resistance threat[1]. Since 1986, the CDC has managed a nationwide surveillance program, the Gonococcal Isolate Surveillance Project (GISP – now incorporated into the Combatting Antimicrobial Resistant Gonorrhea and other STIs (CARGOS) project) in which clinics throughout the United States submit gonococcal isolates to regional laboratories for antimicrobial susceptibility testing; a significant subset of these isolates has been whole genome sequenced.

While intramuscular ceftriaxone is the drug of choice for treatment of gonorrhea in the U.S., rare

[1] https://www.cdc.gov/antimicrobial-resistance/media/pdfs/2019-ar-threats-report-508.pdf

isolates with reduced susceptibility to ceftriaxone have been identified[2]. In December 2025, two new drugs - zoliflodacin and gepotidacin - were approved by FDA for the treatment of uncomplicated gonorrhea[3,4]. Given the challenges with culture of, and traditional susceptibility testing for *N. gonorrhoeae*, identification and characterization of genomic mutations and their impact on phenotypic expression, i.e., changes in MIC, are of considerable scientific and clinical interest. The proposed research study seeks to evaluate molecular and genomic data in the identification of AMR determinants associated with clinically observed resistance, qualitative and quantitative assessment of the impact of these resistance determinants on MIC, and development of methodologies to identify resistance mechanisms to novel drugs.

Research Proposal Objectives

The overall objective of this project is to develop and validate robust genomic approaches to characterize and predict antimicrobial susceptibility and resistance in *Neisseria gonorrhoeae* by integrating whole-genome sequencing data with quantitative phenotypic antimicrobial susceptibility testing (AST). The project will utilize existing CDC genomic and phenotypic datasets, newly generated surveillance isolates, and complementary analytical approaches to identify and characterize genetic determinants associated with antimicrobial resistance in established and newly approved antimicrobial drugs for the treatment of *N. gonorrhoeae* infections.

Research objectives could encompass:

a) Supporting CDC's existing genomic surveillance efforts through whole genome sequencing (WGS) and paired MIC determinations for *N. gonorrhoeae* isolates collected through national antimicrobial resistance surveillance programs.
b) Systematically characterizing molecular resistance mechanisms and evaluating their contributions to observed MIC profiles in clinical and surveillance isolates.
c) Evaluating biological, technical, and epidemiological factors that may influence the relationship between genotypic resistance markers and phenotypic susceptibility results.
d) Developing, optimizing, and evaluating robust methods for detecting and monitoring emerging resistance to newly approved antimicrobial agents indicated for the treatment of gonorrhea.

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 proposal.

The Full Proposal should provide sufficient detail on the planned analyses.

The proposal could address the evaluation and integration of existing genomic datasets to establish a resource suitable for genotype-phenotype analysis, and/or regression and machine learning methods applied to develop and validate genotype-based predictions of antimicrobial susceptibility and

[2] Schlanger K et al; SURRG Working Group. Strengthening the US Response to Resistant Gonorrhea: An Overview of a Multisite Program to Enhance Local Response Capacity for Antibiotic-Resistant Neisseria gonorrhoeae. Sex Transm Dis. 2021 Dec 1;48(12S Suppl 2):S97-S103. doi: 10.1097/OLQ.0000000000001545.
[3] https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/219491Orig1s000lbl.pdf
[4] https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/218230s000lbl.pdf

resistance. Validation of methods, characterization of resistance-associated genotypes, and the capacity to incorporate emerging technology, antimicrobial resistance determinants, and analytical methods are encouraged.

Offerors should include a description of their qualifications, capabilities, related experience, past performance, data management plan, and describe their plan to make research findings publicly available for consideration by the FDA and standards development organizations. 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 FY27 FDA BAA. Offerors must register at SAM (accessed via https://www.sam.gov) to register your entity. This creates a profile for your organization in the U.S. government's system for Award Management. Please also ensure that the postal zip code is listed under both the physical address and mailing address.

The BAA Informational Day will take place on December 8, 2026. We highly encourage new offerors and foreign offerors to attend this virtual meeting as it will provide the Food and Drug Administration's research areas of interest and review valuable information on the application processes specific for the Fiscal Year 2027 Broad Agency Announcement. Visit this website for details: https://www.fda.gov/science-research/advancing-regulatory-science/fiscal-year-fy-2027-fda-broad-agency-announcement-day-12082026

Submission Deadline: January 22, 2027, 5pm ET

- Stage I Package (both Concept Paper and Full Proposal are due by this date)

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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