FY2023 Office of Infectious Diseases Funding Announcement to Evaluate the Useability and Impact of Antimicrobial Drug Labeling for Healthcare Providers

In fiscal year 2023, a research area to "Evaluate the utility and impact of current methods and innovate strategies to communicate FDA evaluations of safety and effectiveness of approved antimicrobial drugs to healthcare providers with the goal of appropriate use of new antimicrobial drugs" has been identified as a priority area by the Office of Infectious Diseases in FDA's Center for Drug Evaluation and Research. Specifically, research proposals focused on methods to evaluate and enhance the functionality and utility of product labeling of antimicrobial drugs to better communicate scientific information to healthcare providers on the optimal use of these drugs (including those that are active against bacteria and fungi resistant to many currently available therapies) will be sought.

Depending on the scientific merit of Full Proposals, the Agency anticipates awarding one research contract on or before September 30, 2023 to address this priority area. The funding for this priority area will not exceed $300,000.

Background

Antimicrobial drug resistance is a major threat to public health. FDA's roles in combatting antibacterial drug resistance include: (1) facilitating the development of new antibacterial drugs to treat patients and (2) advancing the science of clinical trial design. As part of the evaluation of New Drug Applications (NDA) or Biologics Licensing Applications (BLA) for new antibacterial drugs or biologics, FDA reviews product labeling developed by the drug applicant according to requirements delineated in the Code of Federal Regulations (e.g., CFR 201.57) and revises the labeling in collaboration with the applicant based on labeling regulations, guidance recommendations, and the FDA's independent analysis of the drug's effectiveness and safety.

Human prescription drug labeling: (1) contains a summary of the essential scientific information needed for the safe and effective use of the drug and (2) includes the FDA-approved Prescribing Information (PI), FDA-approved patient labeling (Medication Guides, Patient Package Inserts, and/or Instructions for Use), and/or carton and container labeling[1].

All new human prescription drugs approved since June 2001 and certain human prescription drugs approved before June 2001 (e.g., those approved for new uses after June 2001) must have a PI in Physicians Labeling Rule (PLR) format. Advantages of the PLR format labeling[1] are that it:

1) Represents a more useful and modern approach for communicating accurate and up-to-date information on the safe and effective use of drugs,

2) Reduces the number of adverse reactions resulting from medication errors due to misunderstood or incorrectly applied drug information, and

[1] https://www.fda.gov/drugs/laws-acts-and-rules/fdas-labeling-resources-human-prescription-drugs

3) Makes the PI more accessible for use with electronic prescribing tools and other electronic information resources.

While FDA considers the PI to be the primary tool for communicating the essential scientific information needed for the safe and effective use of an antimicrobial drug by healthcare providers, there are limited metrics to evaluate the effectiveness of the PI. Further research is needed to gain insight into the utility, functionality, and impact of current labeling including clarity on the sections that are most useful to healthcare providers prescribing antimicrobial drugs.

Research Proposal Objectives

FDA is interested in understanding:

- How healthcare providers access and utilize the FDA-approved PI for antimicrobial drugs in PLR format, and specifically which sections are most effective and useful to them and why.
- Methods to enhance the effectiveness, useability, and clinical relevance of the FDA-approved PI for antimicrobial drugs, including those drugs that are active against resistant organisms.
- The role of the FDA-approved PI for antimicrobial drugs in decision-making by healthcare providers and formulary committees in various settings including academic centers, regional and community hospitals, and long-term care facilities

Research Proposal Preparation Considerations

FDA will prioritize White Papers and Full Proposals based on program relevance to achieve the objectives outlined above, overall scientific and technical merit, and offeror's capability.

Proposed activities could include:

1. A literature search of studies that evaluate the impact and useability of drug labeling and provision of a written summary.
2. Survey(s) and focus group discussions among different groups of healthcare providers in various settings to formulate a clear picture of how the FDA-approved PI for antimicrobial drugs is currently used, and the perceived gaps in useability and clinical relevance.
3. Recommendations for ways in which the interface between labeling for antimicrobial drugs and healthcare providers can be enhanced.

Proposals also must include a plan to make research findings publicly available.

Offerors should describe any research previously conducted to support their proposal. Additionally, a description of the Offeror's qualifications, related experience, and past performance, including involvement in existing programs that successfully interact with government agencies, international organizations, public or private partners, and other groups (e.g., trade or patient-advocacy groups) should be included.

The contractor will also be responsible for subcontracting with institutions and other collaborators.

Links for reference:

1. https://www.fda.gov/drugs/laws-acts-and-rules/fdas-labeling-resources-human-prescription-drugs

It is anticipated that research contract awards will be made through the FY23 FDA Broad Agency Announcement (BAA). Information regarding proposal preparation and submission as well as specific due dates will be announced in Fall 2022 on Sam.gov website as well as on the Office of Infectious Disease Research Webpage Link at:

https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm536676.htm

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