U.S. FOOD & DRUG ADMINISTRATION

FDA'S SAFE USE INITIATIVE

WHAT WE DO: FDA's Safe Use Initiative[1] is committed to reducing preventable harm from drugs by soliciting and funding projects that develop innovative methods to create, facilitate, and encourage research in the area of safe medication use.

WHO CAN APPLY? Proposals for funding may originate from a broad range of stakeholders, including academia, other government agencies, healthcare professionals and their societies, healthcare entities (e.g., pharmacies, hospitals, health systems), patients, caregivers, consumers, and their representative organizations.

WHAT IS THE PROCESS? Projects are selected and funded via a specialized contract mechanism called the Broad Agency Announcement (BAA). Project proposals are evaluated in two stages. The first step is to submit the research project as a White Paper. The White Paper should describe the proposed project in sufficient detail, in less than 10 pages, to allow evaluation of the project's technical merit and relevance to FDA's mission. If the White Paper receives a favorable rating, a full proposal is invited. Full proposals should provide additional details that provide a more comprehensive view of the project and may be up to 50 pages in length.

Additional details on submitting proposals can be found at FedBizOpps.gov.[2] A corresponding downloadable document with instructions can be found at FDABAA-19-00123.[3] Submissions to Safe Use should be marked with Research Area of Interest 8.5.1.

INTERESTED IN MEETING WITH FDA TO DISCUSS POSSIBLE OPPORTUNITIES?
Unlike many other government contracting processes, the BAA allows discussion between researchers and FDA's Safe Use Initiative Team. We are happy to arrange a call or discuss ideas you might have. It is important to note that these discussions must take place prior to White Paper submission. After the White Paper is received, Federal contracting rules do not allow additional communication between FDA and the submitter until the proposal evaluation has been completed.

WHAT SORTS OF PROJECTS HAVE WE FUNDED? Examples of recently funded Safe Use Initiative projects can be found at: Safe Use Initiative - Extramural Research[4]

HOW DO YOU CONTACT US? If you have questions or would like to schedule a meeting, you can contact the Safe Use Initiative Team at CDERSafeUseInitiative@fda.hhs.gov
Thank you for your interest in reducing preventable harm from medications.

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[1]https://www.fda.gov/drugs/drug-safety-and-availability/safe-use-initiative
[2]https://www.fbo.gov/index?s=opportunity&mode=form&id=a089932fcb8621eb6b685d084fb315be&tab=core&_cview=1
[3]https://www.fbo.gov/utils/view?id=b0cff7fd82c210175f85e7aee3ab16a9
[4]https://www.fda.gov/drugs/safe-use-initiative/safe-use-initiative-extramural-research

DESIRABLE QUALITIES OF RESEARCH PROPOSALS SUBMITTED TO THE SAFE USE INITIATIVE

The following are a set of general criteria intended to improve the quality of a research proposal. Although the first two criteria are required, this list is not intended to be a checklist or scoring system:

1. THE SUBJECT OF THE PROJECT MUST BE RELATED TO OR IMPACT A FDA/CDER-REGULATED PRODUCT

The project could focus directly on a CDER-regulated drug or drug class, such as reducing inappropriate prescribing of antibiotics. Alternatively, it might focus on an intervention which might reduce harms from a broad array of drugs, such as a project examining safe storage and disposal of medicines. The harm reduction could involve prescription or over-the-counter drugs, biologic therapeutics, or generic drugs since each of these categories are regulated by CDER.

2. THE PROJECT MUST AIM TO REDUCE A PREVENTABLE HARM

Preventable harm reduction methods can vary and may include: innovative messaging, modifications to EHR systems, use of mobile technology, and systems engineering approaches. While preventable harm can be broadly defined, the project must clearly describe the harm to be prevented or reduced and how the project intends to accomplish this goal.

3. IMPACTFUL

Projects should focus on harm reduction that is clinically meaningful and addresses an unmet public health need. Target areas may include harms that lead to hospitalization, disability, or death; that impact health-related quality of life; or that lead to loss of income or work. Target populations may be broad (e.g., when addressing a common high-burden disease) or may be narrow, focusing on an unmet medical need in a vulnerable population (e.g., very young or elderly, minorities, pregnant women, veterans, economically disadvantaged groups, stigmatized populations, or those with a disability).

4. MEASURABLE OUTCOME

The strongest projects are built around a measurable outcome to assess intervention effectiveness. The outcome can be a direct measure of reduced harm (e.g., deaths, hospitalizations) or an indirect measure (e.g., reduced number of prescriptions, fewer calls to poison control centers). The measured outcome and assessment methods should be clearly described. Formal hypothesis testing (e.g., "We anticipate a 10% reduction in X within 12 months.") is not required.

5. RESULTS SHOULD BE ACTIONABLE AND/OR SCALABLE

Most projects will be modest in size. They may be conducted within a single hospital system or a few clinics. It is important to consider whether the desired outcome would lead to further meaningful action and/or if the intervention could be implemented on a broader scale. (e.g., Would an intervention that is successful in one health care system/setting be generalizable to and practically adopted by another?) Safe Use favors projects that offer more potential to be widely adopted.

6. INNOVATIVE METHODS

Projects that use innovative methods or combine methods in novel ways are encouraged. Methods may include big data analytics, mobile technologies, or integration of information technology systems.