

PRESOLICITATION NOTICE

Development of Radiation/Nuclear Medical Countermeasures (MCMs) And Biodosimetry Devices BAA NUMBER 75N93024R00020

Presolicitation Notice Information

Introduction

The National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), of the Department of Health and Human Services (DHHS) has been charged by the DHHS with developing products for the assessment, diagnosis, mitigation and/or treatment of radiation injuries resulting from a radiological or nuclear incident, to advance these approaches to the stage where they are competitive for advanced product development by the Biomedical Advanced Research and Development Authority (BARDA) or acquisition under the Project BioShield Act of 2004.

Description

NIAID intends to solicit proposals for contracts entitled "Development of Radiation/Nuclear Medical Countermeasures (MCMs) And Biodosimetry Devices" to advance the development of candidate biodosimetry signatures/devices or MCMs to assess injuries and/or reduce mortality and/or major morbidities associated with exposure to radiation during a radiation public health emergency. NIAID anticipates that research and development studies supported by this Broad Agency Announcement (BAA) will advance lead biodosimetry signatures and devices or candidate MCMs toward eventual FDA clearance, approval, or licensure. For this BAA, it is anticipated that candidate biodosimetry signature or lead MCMs will enter the evaluation and development pathway at various stages, from mid-stage research to post-marketing (for assays/tests or drugs/biologics that are already licensed or approved for other indications), so the offeror is expected to provide a Statement of Work (SOW) based on the stage of the candidate and the work that needs to be performed to advance the biodosimetry signature/device or lead MCM.

Proposals will be evaluated on the availability of data supporting detection of exposure or prediction of radiation injuries or the amelioration by a candidate MCM of radiation-induced tissue damage and reduction of mortality and/or major morbidities. Also considered will be the adequacy of the proposed scientific approach and methodology used to support the advancement of the candidate biodosimetry signature/device or MCM for the diagnosis, mitigation or treatment of the acute radiation syndrome (ARS) or delayed effects of acute radiation exposure (DEARE) toward U.S. FDA approval, licensure, or clearance (under the FDA Biodosimetry Guidance or the FDA Animal Rule for MCMs). The evaluation will also be based on the adequacy of the scientific and technical personnel, facilities, equipment, GLP, cGMP compliance (if applicable) and project management.

It is anticipated that 1-2 cost reimbursement, completion type contracts will be awarded for a 3-year period of performance beginning on or about March/April 2026.

NIAID estimates that the average annual total cost (direct and indirect costs combined) for a non-severable base period and each subsequent, non-severable, completion option period will average \$2 million, for a total award of up to \$6 million over three years. However, it is anticipated that the total cost for the award(s) may vary depending upon the scope of the

project and the technical objectives of the award(s). The length of time for which funding is requested should be consistent with the nature and complexity of the proposed research. In no event shall the period of performance proposed by an offeror exceed 3 years.

Any responsible offeror may submit a proposal which shall be considered by the Agency. This BAA will be available electronically on/about December 19, 2024, and may be accessed through [SAM.gov](https://sam.gov). This notice does not commit the Government to award a contract. No collect calls will be accepted. No facsimile transmissions will be accepted.

For this solicitation, the NIAID requires proposals to be submitted via the NIAID electronic Contract Proposal Submission (eCPS) website. Submission of proposals by facsimile or e-mail is not acceptable.

For directions on using eCPS, go to the website <https://ecps.nih.gov/> and then click on "How to Submit."