Request for Information (RFI): Development of Radiation/Nuclear Medical Countermeasures, Predictive Biomarkers, and Biodosimetry Devices

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Key dates:

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Response Date: May 26, 2015

Related Announcements
None

Issued by

National Institute of Allergy and Infectious Diseases (NIAID)

Purpose

This Notice is intended to solicit input from the radiation biology research and product development communities about the current status of Medical Countermeasures (MCMs) for treatment of ionizing radiation injury, biomarkers of radiation injury, and biodosimetry devices that can be used or deployed during or following a radiation/nuclear incident. NIAID is seeking information on:

- MCM candidates that currently have proof of concept data showing efficacy against radiation injury (hematopoietic, gastrointestinal, pulmonary, renal, and vascular/endothelial) when administered 24 hours or later after exposure, and that are suitable for Food and Drug Administration (FDA) licensure, or approval under the Animal Rule;

- Biodosimetry devices and biomarker studies that address the intensity and kinetics of tissue damage, as well as new technologies/devices to measure radiation exposure that can be approved or cleared by the FDA for field application or hospital use to guide medical management decisions.

NIAID will use the information obtained in response to this RFI to design future programs to develop safe and effective radiation MCMs.

Background

The Department of Health and Human Services (HHS) is charged with protecting civilian populations by providing leadership in research, development, acquisition, deployment, and use of effective MCMs for weapons of mass destruction. The HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Implementation Plan for Chemical, Biological, Radiological and Nuclear (CBRN) Threats (http://www.phe.gov/Preparedness/mcm/phemce/Pages/strategy.aspx) provides a blueprint for all
of its MCM-related activities, including MCM against radiological and nuclear threats. NIAID, on behalf of the National Institutes of Health (NIH) has been charged with developing and managing a comprehensive research and development program focused on medical therapies and diagnostics as outlined in the NIH Strategic Plan and Research Agenda for Medical Countermeasures against Radiation and Nuclear Threats (http://www.niaid.nih.gov/about/whoWeAre/Documents/radnucstrategicplan.pdf and http://www.niaid.nih.gov/topics/radnuc/Documents/radnucprogressreport.pdf).

Acute radiation syndrome (ARS) encompasses a spectrum of pathophysiologic changes caused by exposure to mid-high doses of penetrating radiation in a relatively short time period. Injuries sustained depend on the dose and extent of radiation exposure (e.g., whole- or partial-body). Radiation exposures exceeding 2 Gy in human adults can lead to the depletion of hematopoietic stem cells and cellular progenitors in the bone marrow, which can result in severe neutropenia, thrombocytopenia, and death from infection or hemorrhage. Higher radiation doses can cause gastrointestinal (GI) complications, including mucosal barrier breakdown, bacterial translocation, and loss of GI structural integrity, which can lead to rapid death. Individuals who survive ARS may suffer from the delayed effects of acute radiation exposure (DEARE), which can include pulmonary, renal, cardiac, vascular, and cutaneous complications occurring weeks to months after radiation exposure.

Project Requirements:

The NIH is committed to addressing the need for radiation/nuclear MCMs that are suitable for a mass casualty situation and to support research and development efforts to make them available for advanced development and procurement by the Biomedical Advanced Research and Development Authority (BARDA) for the Strategic National Stockpile (SNS). These efforts include developing MCMs against radiation injury, organ-specific, predictive biomarkers of injury, and biodosimetry devices to determine the extent of radiation exposure. For the purposes of this RFI, the terms “MCM(s)” will include biodosimetry methods and devices as well as agents, drugs, biologics, cellular therapies, and other mitigators or approaches that would reduce radiation injury.

Interested organizations that have candidate products are invited to provide a capability statement describing research in the following areas:

- MCMs effective in animal models of radiation injury in one or more radiation sensitive tissues (hematopoietic, gastrointestinal, pulmonary, renal or vascular endothelial compartment) when administration is delayed at least 24 hours post-irradiation.

- Biodosimetry devices that measure radiation dose to distinguish between the exposed and unexposed population (<2 Gy and >2Gy, for example) and biomarkers that predict total body or tissue-specific radiation injury when measured post-radiation exposure – 30 minutes to 24 hours to 7 days post-irradiation.
Information Requested:

Medical Countermeasures:

a) Description of the product including relevant physico-chemical or immunological characteristics;
b) Description of the proposed mechanism of action for radiation mitigation of the product in the relevant radiation models;
c) Description of the efficacy of the product in animal models;
d) Description of drug formulation, dosage, route, and timing of administration with respect to time of irradiation,
e) description of the animal model(s) used;
f) Statement of the proposed indication(s) for use; and
g) Overall stage of product development (Technology Readiness Level – TRL) as set forth by PHEMCE; https://www.medicalcountermeasures.gov/federal-initiatives/guidance/integrated-trls.aspx and regulatory development, including the current status of preclinical and clinical safety, toxicology, pharmacokinetics and efficacy studies.

Biodosimetry devices and biomarker studies:

- Predictive Biomarkers:

  a) Identification of specific tissue biomarkers following radiation that predict severity of radiation injury;
  b) Description of the biokinetics of the biomarkers;
  c) Description of the acceptable testing window ranges from 30 minutes to 24 hours to 7 days or later post-exposure);
  d) Description the limitations of the method or biomarker assay (e.g., testing in at risk populations (i.e., newborn to elderly, chronically-ill, etc.), confounding results due to different quality of radiation, populations (gender, age, ethnicity, health status), pre-existing conditions, influence of MCMs, and/or influence of physical trauma in addition to the radiation injury).

- Biodosimetry Device:

  a) Describe the stage of response for which your device is intended, e.g., the device is designed for preliminary triage purposes following a mass exposure event, or for medical management in a hospital setting at later post-exposure times;
  b) For a triage indication, specify throughput capabilities, turnover time for the assay, as well as sample information (type f sample, volume, quantity, ease of accessibility);
  c) Describe assay limitations, accuracy, and analytical range. Include the influence of confounders of the assay including, but not limited to, matrix used for assay, interactions with common drugs, or biological response.
Organization:

Describe in general the structure of the organization and its administrative capabilities, facilities, expertise and experience in the research and development of radiation MCMs.

Responses:

RFI responses should be directed to the NIAID Division of Allergy, Immunology and Transplantation, Office of Acquisitions, Contract Specialist, Albert Nguyen, nguyenal@niaid.nih.gov on or before May 26, 2015.

RFI response must include: 1) name and title of the primary point of contact for the response; 2) name and address of the institution or company; 3) email address and phone number of the primary point of contact.

Responses should be limited to 10 pages and e-mailed as an attachment (Microsoft Word or PDF) to the attention of Albert Nguyen (nguyenal@niaid.nih.gov). A list of relevant scientific references or URLs may be provided separately. Submitted data and information will not be returned.

Disclaimer and Important Notes:

This notice does not obligate the Government to award a contract or otherwise pay for the information provided in response. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice should ensure that its response is complete and sufficiently detailed. Information provided will be used to assess tradeoffs and alternatives available for the potential requirement and may lead to the development of a solicitation. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted.

Any solicitation resulting from the analysis of information obtained will be announced to the public in Federal Business Opportunities in accordance with the FAR Part 5. However, responses to this notice will not be considered adequate responses to a solicitation.

Confidentiality:

No proprietary, classified, confidential, or sensitive information should be included in your response. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s).

Inquiries:

Responses to this RFI and questions about this RFI should only be submitted in writing to the contract specialist Albert Nguyen, at nguyenal@niaid.nih.gov.