NIH/NIAID Radiation and Nuclear Countermeasures Program

Background

In 2004, the National Institute of Allergy and Infectious Diseases (NIAID) was directed by the U.S. Department of Health and Human Services (HHS) to develop a robust research program on behalf of the National Institutes of Health (NIH) to accelerate the development and deployment of radiation/nuclear medical countermeasures (MCMs) for the Strategic National Stockpile. NIAID-sponsored activities focus on MCMs and biodosimetry devices to be used in mass casualty radiation/nuclear incidents involving improvised nuclear devices or radiological dispersal devices.

The NIH/NIAID Radiation and Nuclear Countermeasures Program (RNCP) supports earlyto mid-stage research to develop medical products that mitigate or treat injuries that may result from radiation exposure. In addition, NIAID program staff is available to offer valuable scientific, technical, and regulatory guidance on the process of taking a research idea from its inception through the complex process of product development and licensure.

Research Priority Areas

The research priority areas of the program are to develop the following:

- Drugs that can mitigate and/or treat radiation injury or that can remove radioactive materials from the body. These drugs must
 - Be able to be administered at least 24 hours after radiation exposure
 - Be safe and easy to give to large numbers of people, including special populations such as young children, the elderly, and those with underlying diseases
 - Have broad activity and a long shelf life
- Biodosimetry methods or devices that are
 - Minimally invasive
 - Capable of identifying and measuring absorbed radiation due to internal and/or external radiation exposure
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 - U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES National Institutes of Health National Institute of Allergy and Infectious Diseases

- Able to rapidly and accurately distinguish people who need treatment from those who do not

For more information on these research priority areas, visit http://www.niaid.nih.gov/topics/radnuc/.

What We Offer—Funding Opportunities

Investigators are encouraged to visit the Current Opportunities Web page at http://www.niaid.nih.gov/ topics/radnuc/funding/Pages/currentOpportunities.aspx for all NIAID grant and contract funding opportunities. These opportunities are released throughout the year and can include the following:

- Requests for applications
- Requests for proposals
- Program announcements
- Small business innovation research (SBIR) grants
- Pilot project funding through the Centers for Medical Countermeasures against Radiation (CMCR) program

Investigators working on promising ideas at the early stages of product development can apply for pilot project funding through the NIAID CMCR program. The CMCR program supports research in radiation biology as well as projects to develop diagnostic tools to measure radiation exposure and therapeutics to treat tissue injury. Each center is funded to conduct its own research and support pilot projects proposed by external investigators. Information generated from pilot projects can provide investigators with important preliminary data for inclusion in their future grant, contract, or SBIR applications.

To read about current CMCR projects and find a list of participating institutions, please visit http://www. niaid.nih.gov/topics/radnuc/funding/Pages/awardees. aspx#grant.

The Current Opportunities Web page (http:// www.niaid.nih.gov/topics/radnuc/funding/Pages/ currentOpportunities.aspx) also is a clearinghouse for select funding opportunities from other U.S. government agencies, such as the Biomedical Advanced Research and Development Authority (BARDA), the U.S. Department of Defense (DoD), the U.S. Department of Energy, the National Cancer Institute, the Armed Forces Radiobiology Research Institute, and the National Aeronautics and Space Administration.

What We Offer—Medical Countermeasures Product Development Support Services

The NIH/NIAID Radiation and Nuclear Countermeasures Program can provide the following support services to investigators whose products show promising results:

- Independent confirmation of product efficacy in well-validated, small and large animal models of gastrointestinal, hematopoietic, and lung syndromes resulting from radiation exposure
- Toxicological, pharmacological, and drug candidate synthesis/stability studies to gather data that can assist investigators in their applications for additional sources of funding
- Pivotal animal-model studies of efficacy
- Studies conducted under Good Laboratory Practices standards in small and large animal models as required by the U.S. Food and Drug Administration (FDA) Animal Rule for product licensure
- Additional studies to enable companies to advance products toward FDA licensure

What We Offer—Guidance to Academic and Commercial Investigators

NIAID encourages investigators to contact our program staff for advice and guidance on how to move products from the initial idea, through the basic research and discovery stages, and forward into more advanced stages of development and licensure (such as those sponsored by our product development support services).

Our staff complements and works closely with representatives from BARDA, DoD, and FDA. With this additional expertise, NIAID staff also can provide guidance on issues related to more advanced product development, for example:

- Working with BARDA, DoD, and other NIH institutes to move a product to the advanced development stages
- Interfacing with FDA

- Assessing the technology readiness level (maturity of an evolving technology) of a medical countermeasure or biodosimetry device
- Developing animal models
- Finding sources of funding outside of HHS and DoD

For those companies that are ready to move into medical countermeasures product development, NIAID can facilitate meetings with major U.S. government organizations—BARDA, DoD, FDA, NIH—that have an interest in emergency preparedness and funding for medical countermeasures products.

- If you are an academic investigator, contact Andrea DiCarlo-Cohen, Ph.D., at 301-451-9199 or cohena@niaid.nih.gov.
- If you represent a company, contact Carmen Rios, Ph.D., at 301-451-3230 or carmen.rios@nih.gov.

Additional Information

Armed Forces Radiobiology Research Institute http://www.usuhs.mil/afrri/

HHS BARDA

http://www.phe.gov/about/barda/

FDA Emergency Preparedness and Response http://www.fda.gov/EmergencyPreparedness/

NIH BrIDGs Program

http://www.ncats.nih.gov/bridgs.html

Project Bioshield Act of 2004

http://georgewbush-whitehouse.archives.gov/infocus/ bioshield/

U.S. Department of Defense

http://www.defense.gov/





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