

NIAID Radiation and Nuclear Countermeasures Program

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NIAID Radiation and Nuclear Countermeasures Program

In 2004, NIAID was directed by HHS to develop a robust research program to accelerate the development and deployment of radiation/nuclear medical countermeasures (MCMs) for the Strategic National Stockpile.

Mission:

- Support early to mid-stage research to develop radiation/nuclear MCMs and biodosimetry devices
- Provide funding opportunities:
 - Grants, collaborative agreements, contracts, inter- and intra-agency agreements

Research priorities:

- Drugs to treat or mitigate radiation injury 24hrs post-exposure
- Drugs to remove radioactive materials from the body
- Biodosimetry tools to determine levels of radiation exposure



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NIAID Radiation and Nuclear Countermeasures Program Mission Space

Acute Radiation Syndrome (ARS) & Delayed Effects of Acute Radiation Exposure (DEARE)

- Hematopoietic, gastrointestinal, lung, skin, central nervous system, kidney, combined injury

Late Effects

- Cardiovascular, immunologic, metabolic, cognitive, respiratory

MCM Mechanisms of Action

- Anti-oxidants, anti-inflammatories, anti-apoptotics, growth factors, cytokines, proliferation and differentiation factors, cell-based therapies, etc.



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NIAID Radiation and Nuclear Countermeasures Program Mission Space

Radionuclide Threats


- Am-241, Co-60, Cs-137, I-131, Ir-192, Po-210, Pu-238/239, Sr-90, U-235

Radionuclide MCMs include:

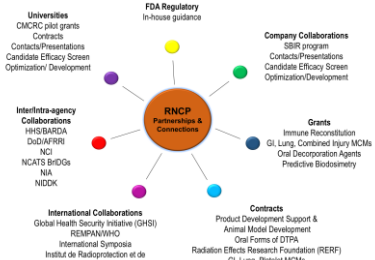
- Blocking agents
- Decorporation agents
- Enhancement of mucociliary clearance


Biodosimetry Markers, Methods & Devices

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NIAID Radiation and Nuclear Countermeasures Program Elements






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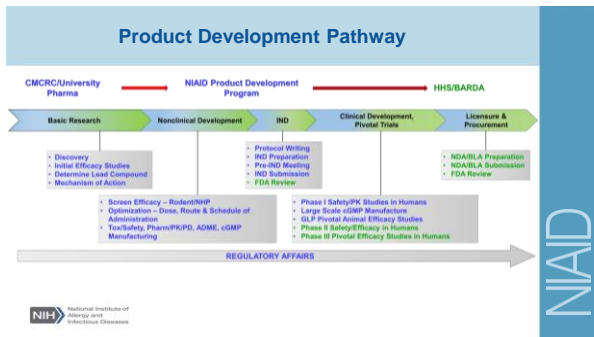
NIAID Radiation and Nuclear Countermeasures Program Research and Product Development Opportunities

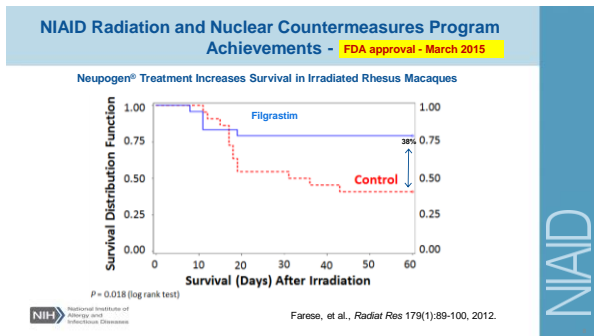
Early Stages		Efficacy Studies		Advanced/Companies	
Centers for MCMs Against Radiation Consortium Columbia University Duke University UCLA University of Pittsburgh	R01/U01 Grants Early-stage MCMs Lung, GI Immune System Geriatric Mouse Model Pediatric Mouse Model	Contracts Mid-stage MCMs, RERF Biodosimetry Biomarkers/Devices Radiation Effects Research Foundation Combined Injury Models	Animal Research Radiobiology Research Institute (ARRI) Home, NHP & Mouse Efficacy Studies Pediatric Mice Model Radiation Effects Research Foundation	SRI International Product Development Support Contract Home, GI & Lung Mouse, Dog & NHP Efficacy Studies GLP Studies Drug Formulation and Synthesis	SBIR Grants Phase I Phase II Innovation Corps (iCorps) Entrepreneurial Training Commercial Readiness Pilot (CRP)
				NCATS BridGs Drug Formulation Redesign Pre-clinical Synthesis	

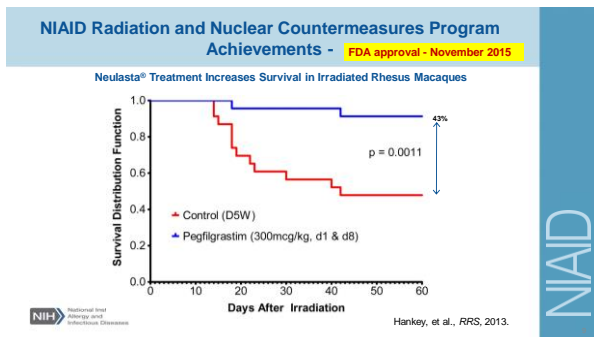


Dosimetry Harmonization using Phantoms with NIST calibrated Thermoluminescent Dosimeters (TLD)

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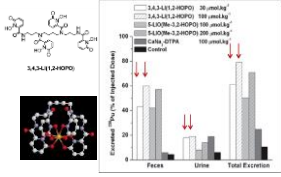






NIAID Radiation and Nuclear Countermeasures Program Achievements

FDA letter to proceed with first-in-human safety/PK evaluation of an oral radionuclide decorporation agent (Hydroxypyridione - 3,4,3(1,2 - HOPO))



FDA IND filed July 7, 2014

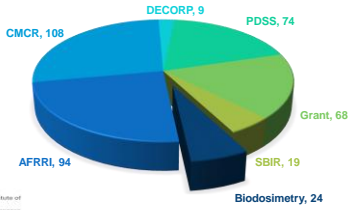


Abergel & Raymond, Hemoglobin 35(3): 276-290, 2011

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NIAID Radiation and Nuclear Countermeasures Program Overview

EVALUATION OF >150 MCM CANDIDATES



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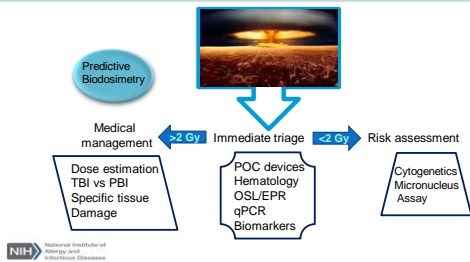
Discovery and Development of Biomarkers for Acute and Delayed Radiation Injuries

- The **objective** is to identify and characterize biomarkers and/or techniques to predict radiation injury to specific organs and tissues of physiological systems
- The **biomarkers** should be linked to relevant clinical outcomes such as organ failure, other major morbidity and/or mortality, strictly related to the radiation exposure and stable for at least 24hr post-exposure



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NIAID Radiation and Nuclear Countermeasures Program Biodosimetry Architecture



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NIAID Radiation and Nuclear Countermeasures Biodosimetry Programs

Predictive Biodosimetry R01 Grants (2012)

- Dana-Farber Cancer Institute
- Fred Hutchinson Cancer Research Center
- Georgetown University
- Medical College of Wisconsin
- UCLA
- University of Rochester

NIAID-NCI IAA (2005-present)

- Gamma H2AX
- Metabolomics
- miRNA

SBIR Grants (2009-present)

- Microfluidic chips for detection of senescent cells
- Optically-based device for detection of miRNA biomarkers

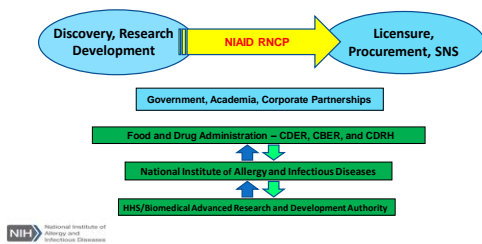
Columbia CMCRC U19 (2005-present)

- Gene expression
- High-throughput cytogenetics
- Metabolomics



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NIAID: Bridging the "Animal Rule Pathway"



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**NIAID Radiation and Nuclear Countermeasures Program
Our Team**

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