



NASA SBIR 2018 Phase I Solicitation

H12.01 Radioprotectors and Mitigators of Space Radiation-induced Health Risks

Lead Center: LaRC

Participating Center(s): JSC

Technology Area: TA6 Human Health, Life Support and Habitation Systems

Space radiation is a significant obstacle to sending humans on long duration missions beyond low earth orbit. NASA is concerned with the health risks to astronauts following exposures to galactic cosmic rays (GCR), the high-energy particles found outside Earth's atmosphere. Astronaut health risks from GCR are categorized into cancer, late and early central nervous systems (CNS) effects, and degenerative risks, which includes cardiovascular diseases (CVD) (see references below for more detail).

This subtopic is for biological countermeasures to minimize or prevent adverse health effects from space radiation: chronic, low dose, low dose-rate, mixed field (high LET and low LET) and mission relevant doses (0.25 to 0.5 Gy). Radioprotectors or mitigators are needed that can target common pathways (e.g., inflammation) across cancer, cardiovascular disease, and neurodegeneration. The focus of this subtopic will be to address CVD and late CNS effects through a medical countermeasure that can provide cross-risk mitigation (addressing both CVD and CNS late effects).

This subtopic will consider:

- FDA approved drugs.
- FDA Off-label usage drugs.
- FDA IND Status drugs.

Biological countermeasures under development for acute radiation syndrome or prevention of secondary radiation-induced diseases from radiation therapy may be ideal for this topic and allow the company to expand its product line to space radiation, carbon ion therapy and ground based late effects from nuclear fallout. Additionally, countermeasures must be acceptable for use as a radioprotectant in an otherwise healthy population with consideration given to safety, risks, and benefits of possible long-term usage over the course of a mission and/or post mission timeframe. Benefits should clearly outweigh risks.

The biological countermeasure criteria:

- Medical products and regimens that prevent and/or mitigate adverse health effects due to space radiation with emphasis on broad activity (i.e., multi-tissue).
- Mechanism of action well known.
- Independent of sex.

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- Capable of being delivered chronically for the period of the mission (potentially up to 3 years).
 - Easily administered; capable of self-administration (e.g., Oral, inhaled).
 - Known/potential benefits greater than known potential risks; minimal adverse events.
 - No contraindications with other drugs used for treating other symptoms or diseases during the mission.
 - Long shelf-life.

Phase I will test radioprotectors or mitigators using mixed radiation fields that must include a low LET source such as gamma combined with high LET radiation such as neutrons or alpha particles to determine efficacy in mixed fields at space relevant doses. This testing can be done at the location of choice. Companies should provide a test plan that will demonstrate the compound being proposed provides protection or mitigation of radiation-induced injury for normal tissues and does not protect cancer cells. A kickoff meeting with NASA is mandatory prior to the start of this award.

Phase II will test effective radioprotectors or mitigators in space radiation simulated environments (HZE) to determine if they are able to minimize or prevent late effects directly related to the development of neurodegeneration or cardiovascular disease. Companies should provide a test plan for in vivo evaluation that describes the expected effect from the compound. Access and funding to support testing in space radiation simulated facilities will be provided for Phase II in addition to the standard award.

The following references discuss the different health effects NASA has identified as areas of concern as a result of space radiation:

- Evidence report on central nervous systems effects - <https://humanresearchroadmap.nasa.gov/evidence/reports/CNS.pdf>.
- Evidence report on degenerative tissue effects - <https://humanresearchroadmap.nasa.gov/evidence/reports/Degen.pdf>.
- Evidence report on carcinogenesis - <https://humanresearchroadmap.nasa.gov/evidence/reports/Cancer.pdf>.