Although crewmembers undergo intensive medical screening, the possibility of crew injury or illness can never be completely eliminated. A mission could be jeopardized or compromised by reduction of able crewmembers, both directly and indirectly if an incapacitated crewmember requires nursing or care. Mission architecture limits the amount of equipment, consumables, and procedures that will be available to treat medical problems. Mission allocation and technology development must be performed to ensure that the limited mass, volume, power, and crew training time are used efficiently to provide the broadest possible treatment capability. There is also a gap in knowledge in how the spaceflight environment affects the effectiveness of drug therapies. This subtopic aims to mitigate those space mission constraints by means of innovative approaches for addressing the knowledge gap in the area of drug stability during long duration spaceflight.

This subtopic seeks proposals for novel approaches to develop an in-flight tool capable of monitoring stability of pharmaceuticals (ideally, solids, liquids and creams) under low gravity conditions. Such a device must be able to determine percentage of active ingredients with a preference to also characterize degradation of products while minimizing the amount of pharmaceutical sample consumed in the test. The technology will need to address approaches and methodologies for handling the different forms of pharmaceuticals (pills, liquids, creams) through the use of a flexible sample preparation front-end amenable to the space environment. The proposed technology should be low-resource, low-footprint, and should involve a low volume of supplies/consumables, which do not require refrigeration or freezing for storage. Also, the technological innovation should be user-friendly, requiring minimal training and operating via uncomplicated protocols.

The Phase I technology developed under this SBIR should investigate one or more one or more of the following drugs:

- Acetaminophen.
- Azithromycin.
- Injectable epinephrine.
- Lidocaine topical gel.
In the Phase I effort, the proof of concept analysis should be demonstrated by the innovative technology and provide comparable results to drug stability laboratory USP standards (i.e., high performance liquid chromatography, differential scanning calorimetry, UV/FTIR spectroscopy). Phase II will seek to optimize these results for additional drugs as well as sensitivity, compound identification, drug degradation products, analysis time and facilitated end-user protocols.

NASA Deliverables: Prototype functional system in a proof of concept analysis demonstrated by the innovative technology producing drug stability characterization including integrity and percentage of active ingredients and characterization/degradation of products (in Phase I). Drugs to be demonstrated in Phase I include: Acetaminophen, Azithromycin, Injectable epinephrine and Lidocaine topical gel.

*HRP IRP Risks* - Inability to Adequately Recognize or Treat an Ill or Injured Crew Member; Risk of Therapeutic Failure Due to Ineffectiveness of Medication

Technology Readiness Levels (TRL) of 5 or higher are sought.

Potential NASA Customers include:

- ISS Medical Project Element in Human Research Program: