CCRP Product Development Support Services - Preclinical Efficacy Evaluation Resources: Sulfur Mustard Pulmonary Toxicity Model

Background

The goal of NIH Chemical Countermeasures Research Program (CCRP) centralized Product Development Support Services (PDSS) - Preclinical Efficacy Evaluation Resources (PEER) is to assist applicants with acquisition of pilot proof-of-principle efficacy data of candidate MCM(s) against the lethal and/or non-lethal effects of chemical threat agents in established or new models of chemical intoxication. PDSS resources are limited and not intended to sustain the entire spectrum of chemical MCM discovery, research, and development and should not be the sole source of support.

All information provided will be treated as confidential. Participants will retain custody of and have primary rights to the data developed, subject to Government rights of access consistent with current HHS, PHS, and NIH policies.

If approved, studies are performed at **no cost** to the applicant. Investigators seeking these services receive no funding from NIAID, but instead receive products or information generated by NIH-funded contractors on their behalf. NIH will deliver a final study report to the investigator at the end of the study.

PDSS Sulfur Mustard (SM) Pulmonary Toxicity

Inhalation of sulfur mustard (SM) can cause destructive damage to the epithelium of the respiratory tract resulting in acute lung injury, pulmonary fibrosis, etc., potentially leading to severe respiratory distress and death, if untreated. Treatment options following inhaled SM injury are largely limited to supportive care. Thus, there exists a critical need for novel MCMs that are effective in rescuing SM-induced acute and/or chronic long-term morbidity and preventing mortality. Injuries caused by acute exposure to chemicals often manifest similarly or identical to conditions observed in clinical practice, such as acute lung injury, acute respiratory distress syndrome, coagulopathy, and pulmonary fibrosis. Applicants seeking label-expansion indications of already FDA-approved medications and/or those further along in the exploratory or validation stage for a conventional indication are highly encouraged to apply.

What We Offer -

The SM pulmonary toxicity model employs an *in vivo* approach where toxicity progression and MCM efficacy are monitored through survival, clinical observations, body weights, body temperatures, pulse oximetry, bronchoalveolar lavage fluid (BAL) analysis, and histo-pathology.

The proposed pilot study will be limited in scope and aim to facilitate initial characterization of candidate MCM(s) efficacy. Preliminary evidence of therapeutic efficacy, i.e., biological response (preferably *in vivo*) against the actual threat agent OR an acceptable surrogate injury model is required.

To learn more, see "A novel sulfur mustard (HD) vapor inhalation exposure model of pulmonary toxicity for the efficacy evaluation of candidate medical counter-measures (DOI: 10.1080/08958378.2021.1951401)."

Applicant Eligibility Criteria

Utilization of PDSS resources is available to any domestic U.S.-based applicant with promising MCM candidates (and appropriate supporting preliminary data) responsive to the CCRP mission

Who to Contact

To learn more or request preparation instructions for a study pre-proposal, please contact **Dave Yeung, Ph.D.** (Deputy Director, CCRP); dy70y@nih.gov