CCRP Product Development Support Services - Preclinical Efficacy Evaluation Resources

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. Threat agents available under through the PDSS include unrestricted and restricted chemicals, e.g., choking, blister, blood, and nerve agents. 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.

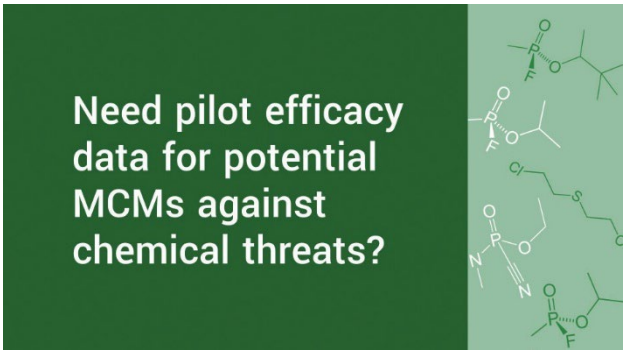
All information provided will be treated as confidential. Participants will retain custody of and have primary rights to the data developed, subject to Government rights of access consistent with current HHS, PHS, and NIH policies.

Before, during, and after the evaluation, the U.S. Government is not required to obtain for the participants any proprietary rights, including intellectual property rights, or any materials needed by the applicant to perform the project. Participants may wish to establish a separate Material Transfer Agreement with the NIH-supported laboratory before commencing any studies, if desired.

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.

Study Criteria

The proposed pilot studies should be limited in scope and aim to facilitate characterization and early optimization of candidate MCM(s) early in the development process. 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.



What We Offer

Pilot studies to facilitate discovery and/or characterization of MCM candidates to prevent chemically induced mortality and/or treat serious morbidities, include but not limited to:

- Development of novel and/or refinement of models of chemical intoxication
- Exploratory proof-of-principle efficacy evaluation in established small laboratory animal models of chemical intoxication, such as:
  - Sulfur Mustard (SM) Pulmonary Toxicity
  - SM Ocular Toxicity
  - SM Hematological Toxicity
  - Soman (GD) Neurotoxicity

Applicant Eligibility Criteria

- Utilization of the PDSS PEER is available to any U.S.-based applicant with promising MCM candidates (and appropriate supporting preliminary data) responsive to the CCRP mission
  - Applicants from foreign institutions and non-U.S. components of U.S. organizations are not eligible to apply
- Need not be a grantee of NIAID nor another National Institutes of Health Institute or Center
- Applicants may consult with NIH to determine eligibility.

Who to Contact

To learn more or request preparation instructions for a study pre-proposal, please contact **Dave Yeung, Ph.D.** (Deputy Director, CCRP); dy70v@nih.gov