# CCRP Product Development Support Services – Preclinical Development Resources

## Background

The goal of NIH Chemical Countermeasures Research Program (CCRP) centralized Product Development Support Services (PDSS) – Preclinical Development Resources (PDR) is to assist applicants with acquisition of non-efficacy data that address specific product development gaps. 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.

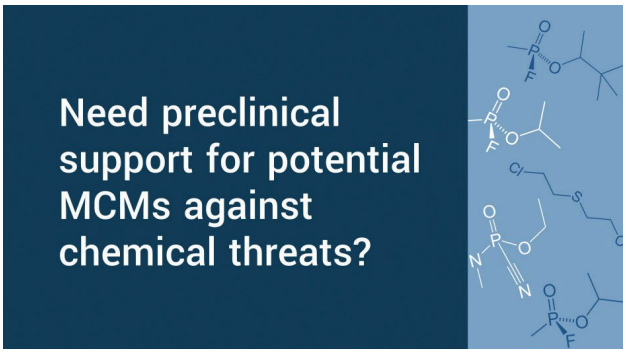
If approved, studies are performed at **no cost** to the applicant. Investigators seeking these services receive no funding from NIAID, but instead receive products or information generated by NIH-funded contractors on their behalf. NIH will deliver a final study report to the investigator at the end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

## Study Criteria

The proposed PDP studies should be limited in scope and aim to facilitate initial characterization and/or early optimization of candidate MCM(s) in the development process. Proposed studies should facilitate characterization and optimization of hits early in the development process by serving as "Go"/ "No Go" decision points for the MCM development effort. Preliminary evidence of therapeutic efficacy, i.e., biological response (preferably *in vivo*) against an actual chemical of concern OR an acceptable surrogate injury model is required.

## Applicant Eligibility Criteria

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




## Examples of PDSS PDP Activities Available

- Initial non-GLP ADMET Services
  - Determination of maximum tolerated dose and no observed effect levels (NOEL)
  - Acute and subchronic toxicity; single and repeated dose toxicity studies
  - Determination of relevant pharmacokinetic and toxicokinetic parameters
  - Bioavailability studies
  - Biotransformation assays conducted *in vitro*
  - Absorption, distribution, metabolism, and excretion studies
  - Various toxicity studies (e.g., genotoxicity, carcinogenicity, reproductive, cytotoxicity, immunetoxicity)
  - Behavioral pharmacology
  - Cell permeability
- Chemistry and Manufacturing Services
  - Developing and performing analytical methods to characterize lead therapeutic agent(s)
  - Formulation and manufacture of lead compounds for in vivo studies
  - Synthesis, resynthesize, or acquisition of reagent grade or clinical grade lead compounds
  - Manufacture laboratory-scale of small quantity and non-GxP quantities of lead MCM candidate(s)
- Development/Review of product development plans

## Who to Contact

To learn about or request Study Pre-Proposal preparation instructions for a, please contact Dave Yeung, Ph.D. (Deputy Director, CCRP); dy70v@nih.gov