

CounterACT Preclinical Development Facility

The NIH NIAID Chemical Countermeasures Research Program (CCRP) offers a preclinical development program through the CounterACT Preclinical Development Facility (CPDF) to support research and early development of potential medical countermeasures (MCMs) against chemical threats. All approved studies are performed at *no cost* to the applicant.

The CPDF program offers initial preclinical safety, toxicity, and pharmacodynamics/pharmacokinetics services, including studies to assess and evaluate the following:

- Maximum tolerated dose and no observed effect level
- Acute and subchronic toxicity (includes single and repeated dose toxicity studies)
- Relevant pharmacokinetic/toxicokinetic parameters
- Bioavailability
- Absorption, distribution, metabolism, and excretion
- Toxicities (genotoxicity, carcinogenicity, reproductive toxicity, cytotoxicity, immunotoxicity, etc.)
- Behavioral pharmacology
- Cell permeability

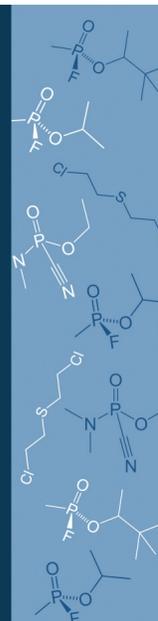
The CPDF program also offers the following chemistry and manufacturing services:

- Developing and using analytical methods to characterize therapeutic agents
- Formulating and manufacturing compounds for *in vivo* studies
- Synthesizing, resynthesizing, or acquiring reagent-grade or clinical-grade compounds
- Manufacturing laboratory-scale quantities of bulk product and proposed formulated product

These limited studies aim to facilitate characterization and optimization of compounds early in the development process by serving as “go/no-go” decision points in the MCM development effort.

Need preclinical support for potential MCMs against chemical threats?

CPDF
may be able to assist.



Eligibility Criteria

In general, the CPDF program is available to all investigators with promising MCMs responsive to the mission of the CCRP. Preliminary evidence of compound efficacy against the actual threat agent *or* an acceptable surrogate agent is required. NIH will accept product development pre-proposals from individual principal investigators (PIs) from academic institutions, government laboratories, and companies. PIs from foreign institutions and non-U.S. components of U.S. organizations are *not* eligible to apply. PIs may consult with NIH to determine eligibility and general product development needs.

Overview of the CPDF Application Process

Each application must be accompanied by a cover letter. The product development pre-proposal should not exceed five pages and must include the following sections:

- **Introduction** providing background information about the compound
- **Justification** describing how the compound meets the eligibility criteria and including a brief



description of efficacy data and any preclinical (safety, chemistry) studies that have already been completed

- **Explanation of Research Needs** providing a general summary of the type of preclinical work that needs to be done

Please request a complete set of application instructions before preparing a pre-proposal. There are no receipt deadlines. NIH will review pre-proposals within 30 days of receipt. Review criteria include, but are not limited to, satisfying the eligibility criteria (efficacy data), impact on the applicant's overall research direction, programmatic priorities of the CCRP, regulatory input from relevant stakeholders, and availability of NIH resources.

If the pre-proposal is approved, the CPDF, in consultation with the applicant and NIH, will prepare a full test implementation plan (TIP) for final review and approval by NIH before the studies begin. TIP preparation typically occurs within 90 days of initial approval of the pre-proposal.

NIH will deliver a final study report to the investigator at the end of the study.

Who To Contact

To learn more about the CPDF or request product development pre-proposal preparation instructions, please contact (preferably by email)

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Additional Information

NIH NIAID Chemical Countermeasures Research Program (CCRP)

<https://www.niaid.nih.gov/research/chemical-countermeasures-program>

NIH Countermeasures Against Chemical Threats Program (CounterACT)

<https://www.ninds.nih.gov/CounterACT>

