



# Preclinical Development for Nano-enabled Strategies



## Fast Facts

- Founded in 2004.
- Offers free preclinical studies for cancer nanomedicines.
- Expertise in pharm/tox, cancer biology, chemistry, immunology, formulation & more.
- Characterized >400 different nanoparticles.
- Worked with >100 universities & companies worldwide.
- Helped advance 14 products into/through clinical trials.
- R&D partner for non-oncology applications, reformulation studies, & more.
- Located in Frederick, Maryland.

## About Us

The Nanotechnology Characterization Laboratory (NCL) is a national resource for all researchers & organizations developing nano-based therapies or diagnostics. In partnership with NCI, NIST and the FDA, the NCL performs vital preclinical studies on nanomedicine candidates to facilitate their clinical translation.

## Our Mission

To expedite the clinical translation of nanomedicine therapeutics and diagnostics. NCL helps national and international researchers move their nano-based products from the discovery phase to clinical trials.

## Collaborative Opportunities

## Our Approach

- Oncology-based nanomedicines are eligible to apply for free preclinical characterization services, funded by NCI.
 

NCL designs and conducts a preclinical study plan tailored to meet the demands of each nanomedicine product. Research plans are designed in collaboration with the submitting investigator. The submitting party retains all intellectual property rights on their formulation.
- R&D services for specific nanomedicine development needs are available at cost—labor, materials and overhead only. NCL does not profit from this work.
- Technical services are available at cost for pre-defined statements of work. Consultation and assistance with data interpretation is available.

Free preclinical testing for cancer nanomedicines

Fee-based work for nanomedicine development



Contact us  
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Frederick National Laboratory  
 for Cancer Research

*sponsored by the National Cancer Institute*

# Collaborative Opportunities

Oncology Nanomedicines  
Free

## Preclinical Characterization

Optimized set of assays - *Assay Cascade*

The NCL developed a set of analytical tests aimed at evaluating the clinical potential of early-development nanomedicine products. This process, the **NCL Assay Cascade**, is available to any researcher developing a nano-product for cancer. Candidates are selected via an application process and selected products are characterized free of charge.

### What We Do

- **Physicochemical Characterization.** Size distribution, composition, purity, surface characteristics, stability & more.
- **In Vitro Toxicological and Immunological Evaluation.** Hematocompatibility, immune cell interactions, cytotoxicity, autophagy & more.
- **In Vivo Efficacy, Toxicity, Pharmacokinetics.** Various tumor & mouse models, single/repeat dose tox studies, clearance & biodistribution, pharmacokinetic profiling & more.

Many Assay Cascade protocols are free to [download](#) from NCL's website.

### Application Process

Applications are accepted quarterly (March, June, September, and December) via a 2-step process.

- I. **White Paper.** Brief 4-page introduction to your technology. The primary evaluation criterion is demonstrated proof of efficacy.
- II. **Expanded Oral/Written Proposal.** Selected White Papers will be asked to submit a Part II proposal, expanding on the technology and addressing any reviewer questions.

## Contact Us for More Info

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All Nanotechnologies  
Fee

## Research & Development

Tailored solutions for all development needs

The NCL leverages its 10+ years of nanotechnology expertise to conduct sponsor-funded R&D. These projects are customized based on the needs of the sponsor. Open to all nanotech strategies.

### What We Do

- **Formulation, Optimization, Lead Selection.** Design and production of nanoformulations to achieve intended biological endpoints. Experience with small molecules, biologics & gene therapies.
- **Bioanalytical Assay Development.** Assay development and validation for lot release, biological activity, bioequivalence & more.
- **Instrument Optimization.** NCL works with instrument developers to improve analytical tools to best meet the needs of the nanotech research community.
- **And more...**Contact us to see how we can help.

Work is initiated through negotiated Contractor Cooperative Research and Development Agreements (cCRADAs) with Leidos Biomedical Research, Inc., the operations and technical support contractor for the Frederick National Lab.

## Technical Services

Pre-defined statement of work

Technical Services are offered for a pre-defined statement of work that does not involve R&D. Currently, NCL offers two Technical Services based on the Stable Isotope Tracer Ultrafiltration Assay (SITUA) – an analytical method invented at NCL that can measure key nanomedicine fractions in plasma.

### Technical Services Available

- NCL-01: In vitro drug release study in human plasma
- NCL-02: Pharmacokinetic study of nanomedicine in rats

Please contact us to discuss scientific details and purchasing procedures.

For details on collaborations, visit: <https://ncl.cancer.gov/working-ncl/process-overview>