



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 >350 different nanoparticles.
- Worked with >100 universities & companies worldwide.
- Helped advance 10 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

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, and they are free to use NCL data however best fits their needs, e.g., IND filing, publication, garner capital. The submitting party retains all intellectual property rights on their formulation.

- Oncology-based nanomedicines are eligible to apply for free preclinical characterization services, funded by NCI.
- R&D services for specific nanomedicine development needs are available at cost—labor, materials and overhead only. NCL does not profit from this work.

Free preclinical testing for cancer nanomedicines

Fee-based R&D services for nanomedicine development

Contact us
ncl@mail.nih.gov
 301-846-6939



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 has 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 nanotechnology-product for cancer. Candidates are selected via an application process and selected products are characterized free of charge.

What We Do

- **Physicochemical Characterization.** e.g., size distribution, composition, purity, surface characteristics, stability, and more.
- **In Vitro Toxicological and Immunological Evaluation.** e.g., hematocompatibility, immune cell interactions, cytotoxicity, autophagy, and more.
- **In Vivo Efficacy, Toxicity, and Pharmacokinetics.** e.g., variety of tumor and mouse models, single and repeat dose tox studies, clearance and tissue distribution, pharmacokinetic profiling, and more.

Many Assay Cascade protocols are published on NCL's website and are free to download.

http://ncl.cancer.gov/working_assay-cascade.asp

Application Process

Applications are accepted 4 times per year, in March, June, September, and December, via a 2-step process.

- I. **White Paper.** Brief 4-page introduction to your technology. The primary evaluation criteria 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 reviewers questions.

http://ncl.cancer.gov/working_application-process.asp

All Nanotechnologies (Fee)

Research & Development

Tailored solutions for all development needs

NCL leverages its 10+ years of nanotechnology expertise to conduct sponsor-funded R&D. These projects are highly customized based on the needs of the sponsor. Any researcher with a nanotech-related need can apply.

What We Do

- **Formulation, Optimization, Lead Selection.** Design and production of nanoformulations to achieve intended biological endpoints. Experience with small molecules, biologics, and gene therapies.
- **Bioanalytical Assay Development.** Development and validation of assays for lot release, biological activity, bioequivalence, and 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.

Application Process

Work is initiated through Contractor Cooperative Research and Development Agreements (cCRADAs) with Leidos Biomedical Research, Inc., the operations and technical support contractor for the Frederick National Lab. cCRADAs are negotiated individually with interested parties. Please contact us for more information.

Contact

Nanotechnology Characterization Laboratory

Frederick National Laboratory for Cancer Research
P.O. Box B
Frederick, MD 21702

Phone: 301-846-6939 | Fax: 301-846-6399

ncl@mail.nih.gov | <http://ncl.cancer.gov>