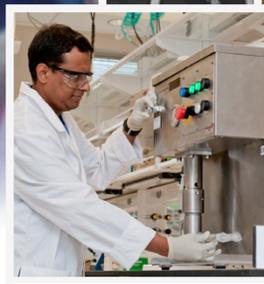
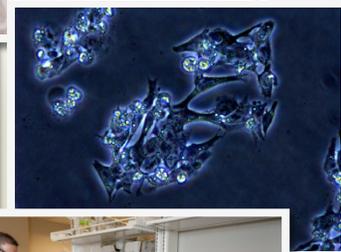
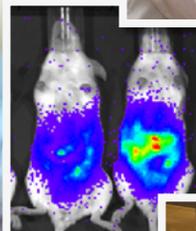
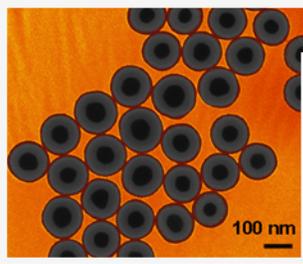




NCI Alliance for
Nanotechnology
in Cancer



About the NCL

Working in concert with the National Institute of Standards and Technology (NIST) and the U.S. Food and Drug Administration (FDA), the National Cancer Institute (NCI) established the Nanotechnology Characterization Laboratory (NCL) to perform and standardize preclinical efficacy and toxicity testing of nanoparticles intended for cancer therapeutics and diagnostics. The NCL provides infrastructure support to NCI's Alliance for Nanotechnology in Cancer and is a national resource and knowledge base for cancer researchers from academia, government and industry, facilitating the development and translation of nanoscale particles and devices for clinical applications.

NCL's activities are markedly speeding the development of nanotechnology-based products for cancer patients, reducing the risks associated with development, and encouraging private sector investment in this promising area of technology.

NCL has experience with a wide variety of nanomaterial platforms, having characterized more than 300 different particles since its inception in 2004. NCL's preclinical characterization services for nanomaterial cancer therapies and diagnostics are available by application and are provided at no cost to accepted applicants.

Benefits to Nanotechnology Developers

Before a company can bring a biomedical nanotechnology product into clinical trials, it must submit either an investigational new drug (IND) application or investigational device exemption (IDE) to the FDA. There is a standard package of data required for IND or IDE submission that includes physicochemical characterizations as well as in vitro and animal studies that provide strong evidence for safety.

The NCL has developed and continues to improve an assay cascade, a set of characterization protocols, from physicochemical studies to animal studies of efficacy and safety, aimed at satisfying most of the FDA's current requirements. The NCL currently has more than 35 standardized assays used in the preclinical assessment of nanomaterials. All materials are submitted to the NCL under a nondisclosure agreement.

Data generated by NCL can be used directly in IND or IDE applications submitted to the FDA, and NCL will defend any NCL-generated data to the FDA. NCL data can also be used in scientific conferences, collaborative publications, and to seek venture capital.



Dendrimers



Liposomes



Polymers



Nanoemulsions



Gold Nanorods



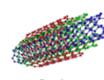
Quantum Dots



Core-Shell



Nanocrystals
(e.g. TiO₂)



Carbon
Nanotubes



Fullerenes



Gold
Colloids



Silver
Colloids

Goals of the NCL

The mission of the NCL is simple: to accelerate the transition of nanotechnology-based research into clinical applications for cancer. To this end, the specific goals of the NCL are:

- Characterize nanomaterials using an analytical cascade of standardized methods.
- Conduct structure activity relationship (SAR) studies to identify and characterize critical parameters related to nanomaterial ADME/Tox.
- Engage in educational and knowledge sharing efforts.
- Facilitate the regulatory review of nanomaterials for cancer clinical trials.

NCL Assay Cascade

NCL characterization services include:

- **Physicochemical Characterization**
 - E.g., size distribution, composition, purity, surface characteristics, and stability.
- **In Vitro Toxicological and Immunological Evaluation**
 - E.g., sterility, hematology, immune cell interactions, cytotoxicity, autophagy.
- **In Vivo Efficacy, Toxicity, and Pharmacokinetics**
 - E.g., xenograft, orthotopic, metastatic and transgenic tumor models, single and repeat dose toxicity studies, disposition studies for clearance, tissue distribution and systemic exposure.

In order to foster the study and evaluation of nanomaterials for clinical applications throughout the research community, assay protocols developed and validated by NCL are freely available via the NCL website.

Thorough characterization is critical for successful translation of a bench-top formulation to clinical application.

Working with the NCL

The NCL accepts proposals for the characterization of nanomaterials from academia, industry and government. Proposals generally represent strategies that incorporate image contrast agents, cancer therapeutics and/or targeting receptors or ligands. A set of entrance criteria is applied to candidate nanotechnology strategies to aid in their selection and prioritization. Nanostrategies proposed to the NCL for characterization are ranked according to the measure of their projected impact on clinical cancer applications and/or furthering nanotechnology's compatibility with biological systems. Specific evaluation criteria include, but are not limited to:

- Previously demonstrated efficacy in vitro and/or in animal models.
- Advantages offered by the strategy over existing cancer therapies or diagnostics.
- Previous physical characterization of the nanomaterial, such as determination of purity and stability.
- The nanostrategy's manufacturing process and compatibility with scale-up.
- The material's inherent toxicity and/or environmental concerns.
- Plans or approach to transition the strategy to clinical trials such as filing the follow-on IND, IDE or pre-IDE.

Applications are accepted quarterly; forms can be downloaded from our website.

For More Information

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