NATIONAL CANCER INSTITUTE

NANOTECHNOLOGY CHARACTERIZATION LABORATORY

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 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. The NCL provides their services at no cost.

NCL's activities are expected to markedly speed the development of nanotechnology-based products for cancer patients, reduce the risk of doing so, and encourage private-sector investment in this promising area of technology development. The NCL will provide a comprehensive set of characterization parameters for nanomaterials and lay a scientific foundation enabling the FDA to make sound decisions concerning the testing and approval of nanoscale cancer diagnostics, imaging agents, and therapeutics.

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:

- Establish and standardize an analytical cascade for nanomaterial characterization.
- Facilitate clinical development and regulatory review of nanomaterials for cancer clinical trials.
- Identify and characterize critical parameters related to nanomaterials' absorption, distribution, metabolism, excretion and acute toxicity (ADME/Tox) in animal models and cell lines.
- Examine the biological characteristics of multi-component nanoscale platforms, including therapeutic, molecular and clinical diagnostic and detection aspects.
- Engage and facilitate academic and industrial-based knowledge sharing of nanomaterial performance data and behavior resulting from pre-clinical testing (physical characterization, *in vitro* testing and *in vivo* pharmaco- and toxicokinetics).
- Interface with national nanotechnology planning and coordination efforts such as the National Nanotechnology Initiative, in cancer research, nanoscience and nanotechnology research, and health, safety and the environment.

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 various physicochemical characterizations as well as *in vitro* and animal studies that provide strong evidence for efficacy and safety. Product sponsors today may not be aware of the important issues that should be addressed in IND submissions of nanomaterials. Submission of a nanotechnology-based product to the FDA that has not been fully characterized increases the risk the IND will be rejected.

Working with the NCL provides a distinct advantage, because of the lab's relationship with the FDA and familiarity with issues that are important to the regulating agency when reviewing biomedical nanomaterials. The NCL has developed and continues to evolve an assay cascade, a set of characterization protocols, from physicochemical studies to animal studies of efficacy and safety, which can satisfy most of the FDA's current requirements.

NCL Assay Cascade

Nanomaterials characterized by the NCL are intended for *in vivo* diagnostic and therapeutic use. Before nanoparticles can be used in patients, however, they must first be evaluated for safety and efficacy by the FDA. To this end, the NCL in collaboration with NIST, has developed and performs a standardized analytical cascade that tests the preclinical toxicology, pharmacology, and efficacy of nanoparticles and devices. 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.

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 will be 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 determining 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 filing the follow-on IND, IDE or pre-IDE.

NCL Partnerships

The activities within the NCL represent a formal scientific interaction of three Federal agencies: the National Cancer Institute (NCI), the U.S. Food and Drug Administration (FDA) of the Department of Health and Human Services, and National Institute of Standards and Technology (NIST) of the Department of Commerce. Scientists from each agency bring critical knowledge, experience, and skills needed to establish information to facilitate clinical technology development.

For More Information

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NCI Alliance for Nanotechnology in Cancer

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