

The National Cancer Institute's Experimental Therapeutics (NExT) Program

Michael J. Difilippantonio, Ph.D.

Program Manager for Therapeutic and Diagnostic
Initiatives, DCTD, NCI

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Division of Cancer Treatment and Diagnosis (DCTD), NCI

- Biometrics Research Branch (BRB)
- Cancer Diagnosis Program (CDP)
- Cancer Imaging Program (CIP)
- Cancer Therapy Evaluation Program (CTEP)
- Developmental Therapeutics Program (DTP)
- Radiation Research Program (RRP)
- Translational Research Program (TRP)
- Office of Cancer Complimentary and Alternative Medicine (OCCAM)

Transformation of the NCI Therapeutics Pipeline



**The NCI Experimental Therapeutics (NExT) Pipeline:
Target discovery through early stage clinical trials**



Harmonize Activities into Single Pipeline

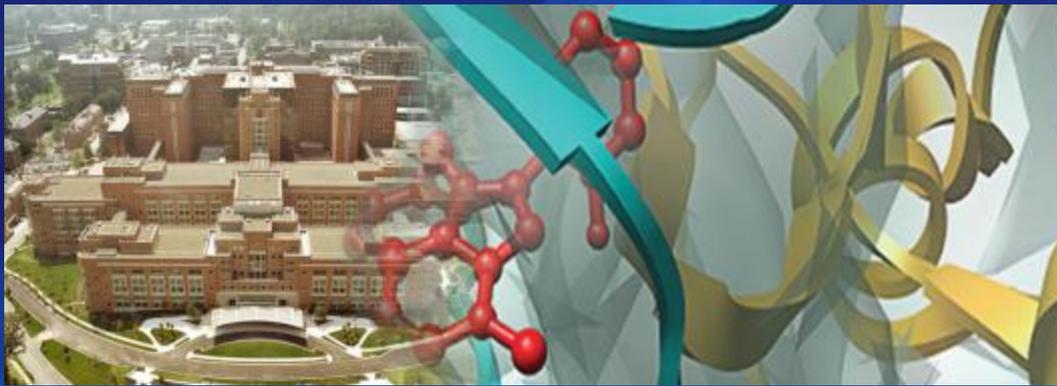
NOT A GRANT PROGRAM

- Clear path to clinic/patient benefit
- Provides access to NCI resources and >50 yrs experience in drug development
- Integrates a variety of prior decentralized and uncoordinated programs
- Simple application
- Applicant is a key member of the team: involved in project planning, implementation, and has full access to data

NExT Resources Currently Support

- Investigational drugs, biologics and NP's
- Investigational imaging agents
- Academic, biotech and pharma projects
- HTS, Hit-to-Lead, Lead Optimization, Clinical Candidate, Phase 1 and 2 clinical trials

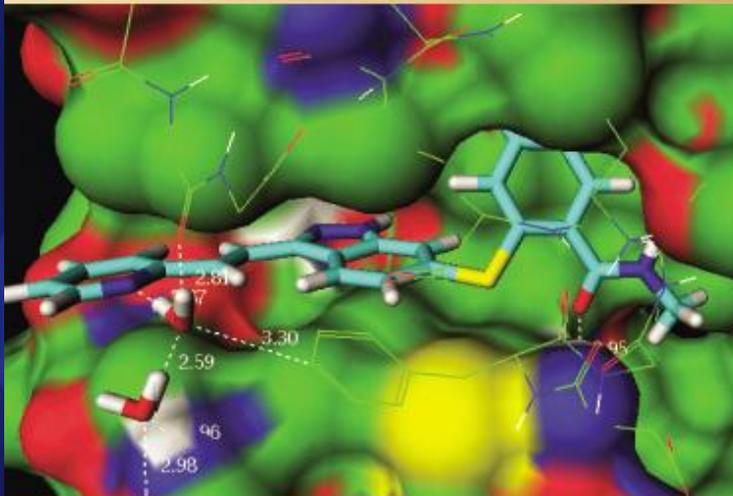
NOT basic research



NExT Discovery Engine

Chemical Biology Consortium

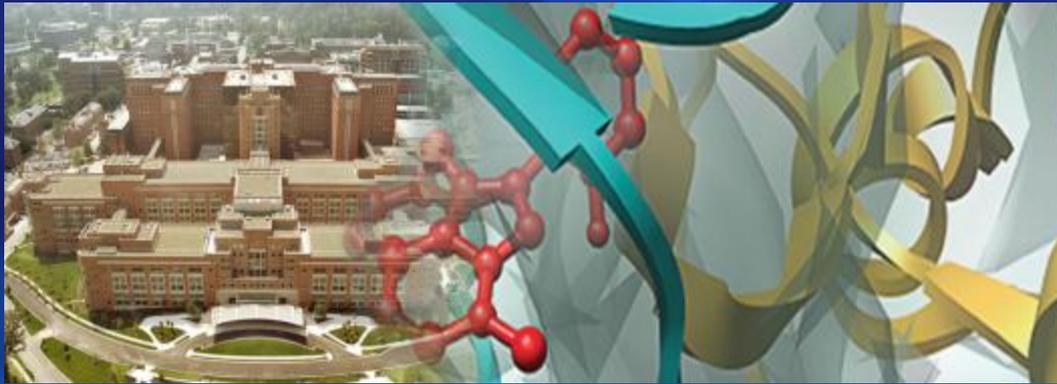
Accelerating the discovery
and development of new
anticancer agents



Dramatically increase the flow of early-stage drug candidates into the DCTD therapeutics pipeline by leveraging knowledge from innovative research and discoveries made at leading academic institutions and biotechnology companies

And

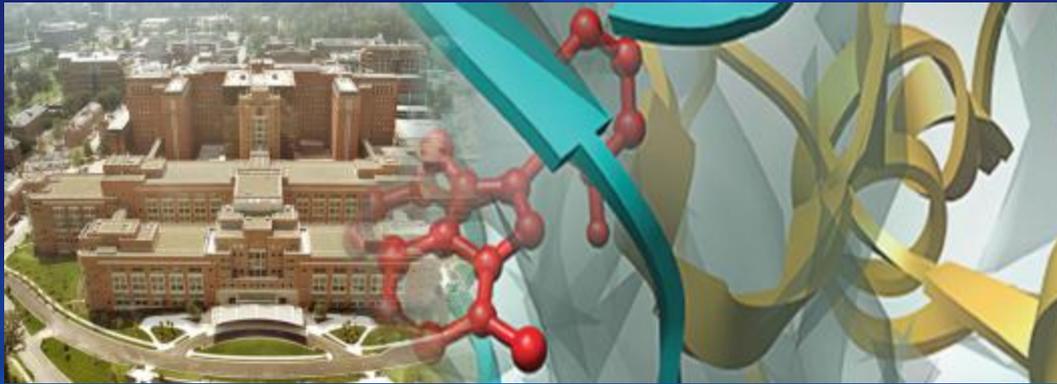
Provide the extramural community the opportunity to participate in a highly collaborative drug discovery partnership with the NCI



NExT Early Development

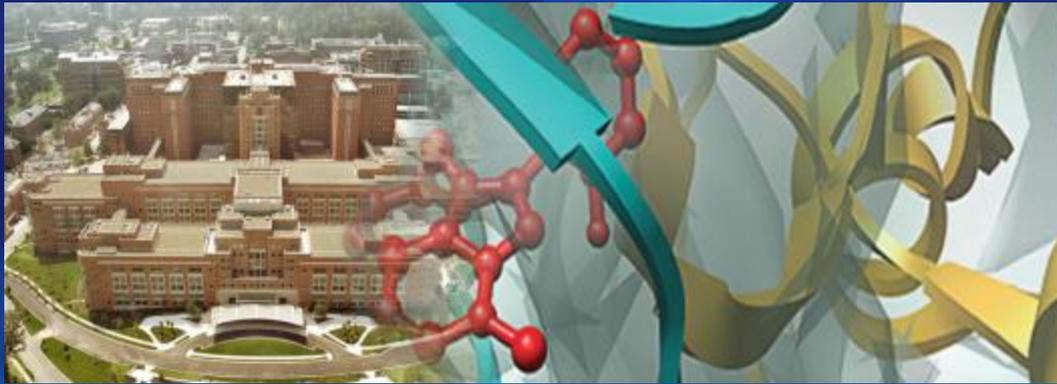
Gain early access to enabling, leading-edge translational technologies and tools

- PK/PD Modeling
- Tox/Safety Pharmacology
- GMP Scale-Up
- Imaging supported by Cancer Imaging Program
- Development and validation of PD assays during preclinical stages is supported by the Pharmacodynamics Assay Development & Implementation Section (PADIS) and during clinical stages by the National Clinical Target Validation Laboratory (NCTVL).
- Clinical Assay Development Program (CADP) development and validation of clinical assays (including diagnostic).



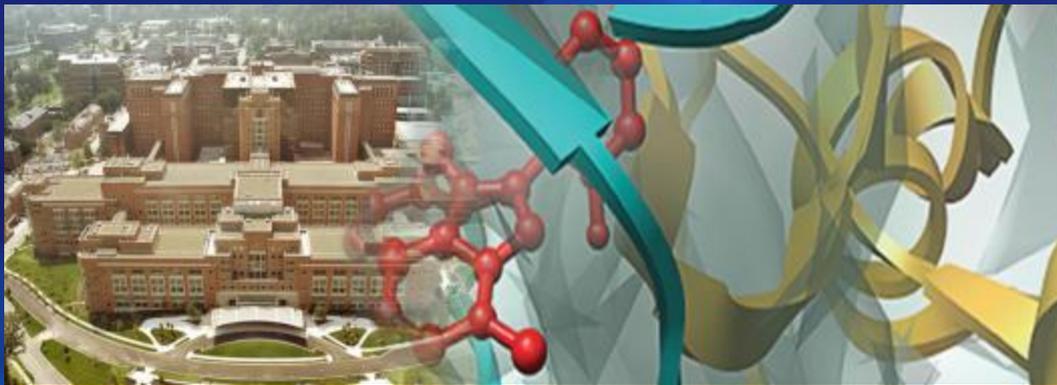
NExT Clinical Development (CTEP)

- Currently sponsors over 100 INDs
- Approx. 11,000 registered investigators at over 3,300 institutions
- Over 750 active protocols
- 150-250 new protocols/year
- Approx. 30,000 patients accrued/year
- **Over 80 collaborative agreements (CRADAs, CTAs, and CSAs) with pharmaceutical companies (Collaborators)**



Application Process

- Concept application – 5 pages
 - Background
 - Hypothesis
 - Research strategy
 - Specific request to NCI
 - Justification
 - Uniqueness
- Appendices
 - IP Information
 - Current and pending support
 - PI biosketch
 - Other Documentation as appropriate



NExT Access



National Cancer Institute

U.S. National Institutes of Health | www.cancer.gov

NExT NCI Experimental
Therapeutics Program

DCTD
Division of Cancer
Treatment and Diagnosis

CCR CENTER FOR
CANCER
RESEARCH

Go>

About NExT

Entry to Pipeline

Pipeline Management

Discovery

Development

Biomarker

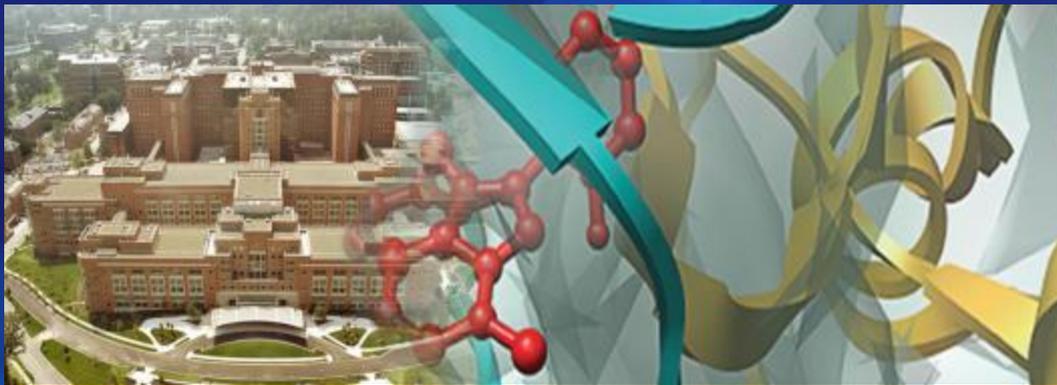
The NCI Experimental Therapeutics (NExT) Program

**A Unique Partnership with the NCI to Facilitate
Oncology Drug Discovery and Development**

Who: Researchers in academia, government, and
industry, nationally or internationally.

<http://next.cancer.gov/>

National Cancer Institute



NExT Submission Dates

Cycle Open for Submission	Submission Deadline
January 15, 2013	February 15, 2013
May 15, 2013	June 15, 2013
September 15, 2013	October 15, 2013



NCI next or next at NCI

Cetuximab

Deoxycoformycin

Lapatinib

Arsenic Trioxide

Thank you for your attention

Dasatinib

Nelarabine

Sunitinib

Romidepsin



Lenalidomide

Temozolomide

Pegaspargase

Sipuleucel

Sarafenib

Topotecan

Eribulin

Bevacizumab



Taxotere

Pralatrexate

Erlotinib

Letrozole

Bortezomib

5-Azacytidine

Oxaliplatin

Imatinib mexylate