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

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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

National Cancer Institute
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**
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.
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).
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
http://next.cancer.gov/
## NExT Submission Dates

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<th>Cycle Open for Submission</th>
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Thank you for your attention!