

# NCAB Ad Hoc Subcommittee on Experimental Therapeutics

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# AGENDA

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- **Welcome**
- **Developmental Therapeutics Program: Review of Scope**
- **Presentation of Proposed Updated Mission Statement**
- **Discussion**

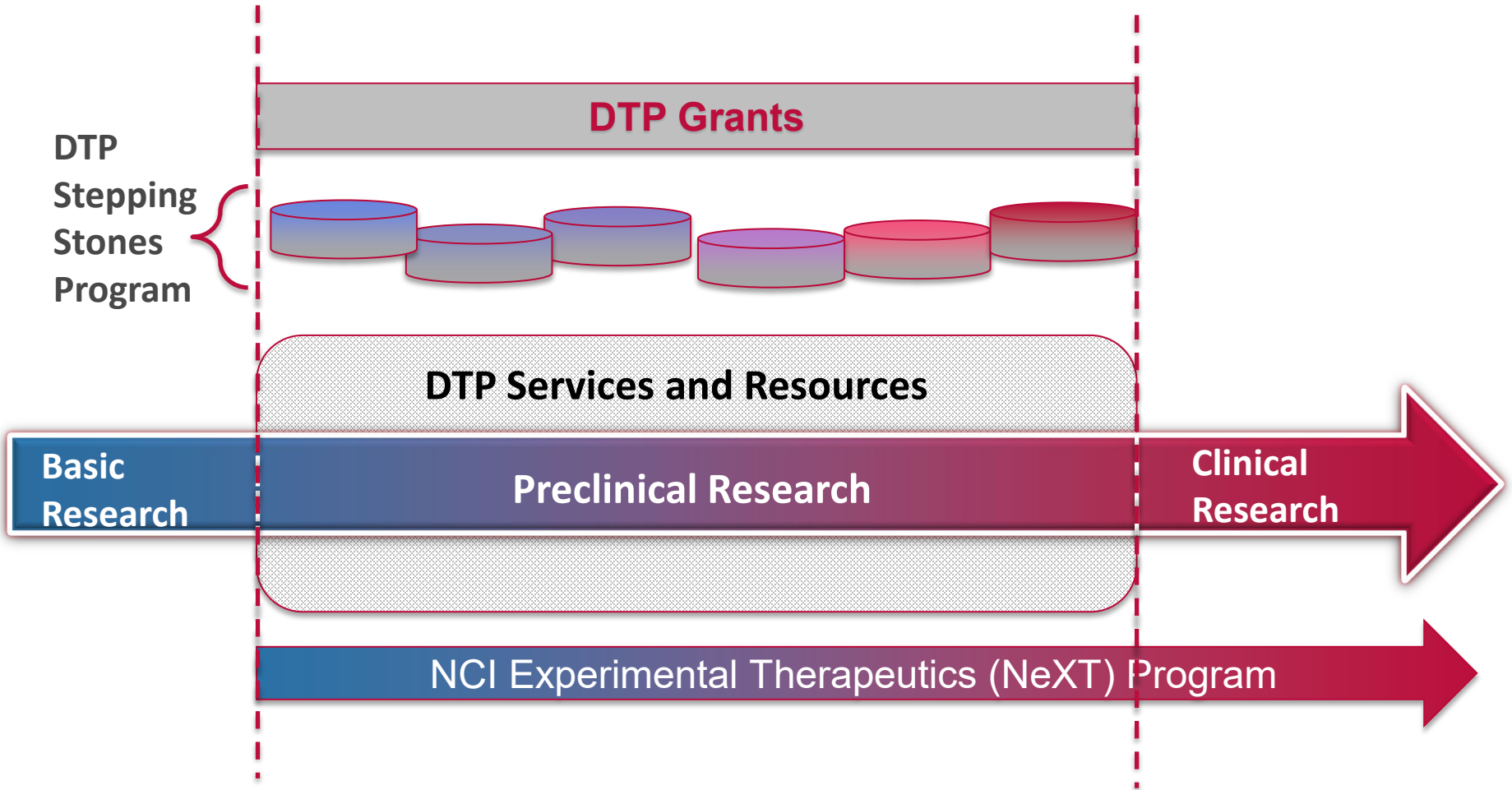
# Division of Cancer Treatment and Diagnosis (DCTD)

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- 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)
- Developmental Therapeutics Clinic (DTC)
- Translational Research Program (TRP)
- Office of Cancer Clinical Proteomics Research (OCCPR)
- Office of Cancer Complimentary and Alternative Medicine (OCCAM)

**DTP Mission: Support and Assist the Extramural Community to Promote Translation of New Therapeutic Concepts Toward Clinical Use**

# DTP: Overlapping Support Mechanisms for Discovery and Development



# DTP Support of NExT: Lead Optimization & Clinical Candidate Readiness

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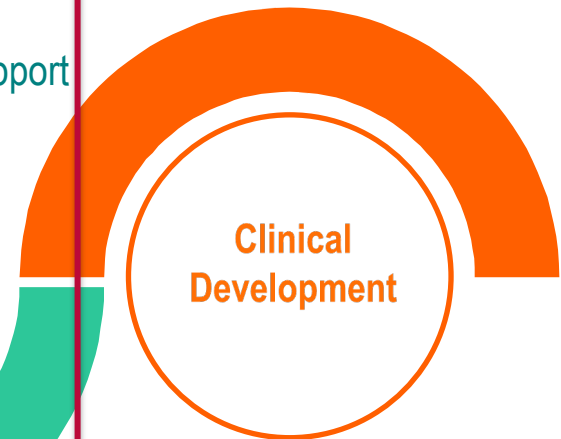
Chemistry Biology Consortium (CBC)  
Focus is small-molecule drug discovery



- Efficacy testing
- Process development
- Assay development
- Range-finding studies
- IND-directed tox/PK
- Formulation Optimization
- GMP manufacturing
- Regulatory affairs support



Clinical Trial support using  
NCI CTEP Clinical Trials  
Networks



## **Mission: Ad Hoc Experimental Therapeutics Subcommittee**

The purpose of this subcommittee is to provide advice and oversight of the NCI Experimental Therapeutics Program (NExT) and to assist the Division of Cancer Treatment and Diagnosis (DCTD) in the translation to the clinic of novel anticancer therapeutic interventions, either synthetic, natural product, or biologic that have been approved for development.

In particular, academic institutions need a bridge between discovery and clinical testing, so that efficient translation of promising discoveries may take place even in the absence of development capacity or clinical expertise in the institution where the discovery was made and the NCI's NExT Program helps bridge this gap. This committee should also foster greater interactions with industry, academia, government, etc. to enhance the drug development process.

This subcommittee will also provide advice on policies, procedures and programs that will enhance the pre-clinical discovery and development of small molecules and biologics.

**Particular emphasis will be to provide oversight of the NCI Chemical Biology Consortium and NExT program.** The goal is to optimize the functionality and output of these programs and to explore the potential contribution of current and future drug discovery and development practices to optimize strategies to preempt cancer at various stages.

*Established: December 2006*

# Process for Updating the Mission Statement

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## 1. Collaboration on drafting the updated statement

**DCTD:** Dr. Rose Aurigemma – Associate Director, DTP, DCTD  
Dr. Christophe Marchand – Deputy Associate Director, DTP, DCTD  
Dr. Toby Hecht – Deputy Director, DCTD  
Dr. Jim Doroshov – Director, DCTD

**NCAB:** Dr. Richard Boxer

## 2. Review and revision by DEA

## 3. Presentation to Ad Hoc Subcommittee on Experimental Therapeutics

## 4. Approval by NCAB

The purpose of ~~this subcommittee~~ the ad hoc Subcommittee on Experimental Therapeutics is to provide advice to the National Cancer Advisory Board (NCAB) and the NCI Director, oversight of the NCI's Experimental Therapeutics Program (NExT) Program, and assistance to ~~assist~~ the Division of Cancer Treatment and Diagnosis (DCTD) in the translation ~~to the clinic~~ of novel anticancer therapeutic interventions to the clinic, either synthetic, natural product, or biologic, that have been approved for development. ~~In particular, academic~~ Academic institutions need a bridge between discovery and clinical testing, so that efficient translation of promising discoveries ~~may take place~~ can occur, i.e., even ~~in the absence of~~ without having development capacity or clinical expertise in the institution where the discovery was made ~~and~~. DCTD resources, such as the NCI's NExT Program ~~helps~~, will/should help to bridge this gap. ~~This committee~~ The ad hoc Subcommittee on Experimental Therapeutics should also foster greater interactions with industry, academia, government, etc., to enhance the drug development process.

~~This subcommittee~~ The ad hoc Subcommittee on Experimental Therapeutics will also ~~provide advice~~ advise on policies, procedures, and programs ~~that will enhance~~ to optimize strategies in the pre-clinical discovery and development of ~~small molecules and biologics. Particular emphasis will be to provide oversight of the NCI~~ novel anticancer therapeutic interventions to ~~Chemical Biology Consortium and NExT program. The goal is to optimize the functionality and output of these programs and to explore~~ address the ~~potential contribution of current acritical translational support needs of the~~ critical translational support needs of the ~~extramural community. nd future drug discovery and development practices to optimize strategies to preempt cancer at various stages~~ extramural community.



## **Proposal: Updated Mission Statement Ad Hoc Subcommittee on Experimental Therapeutics**

The purpose of the ad hoc Subcommittee on Experimental Therapeutics is to provide advice to the National Cancer Advisory Board (NCAB) and the NCI Director, oversight of the NCI's Experimental Therapeutics (NExT) Program, and assistance to the Division of Cancer Treatment and Diagnosis (DCTD) in the translation of novel anticancer therapeutic interventions to the clinic, either synthetic, natural product, or biologic, that have been approved for development.

Academic institutions need a bridge between discovery and clinical testing so that efficient translation of promising discoveries can occur, i.e., even without having development capacity or clinical expertise in the institution where the discovery was made. DCTD resources, such as the NCI's NExT Program, will/should help to bridge this gap. The ad hoc Subcommittee on Experimental Therapeutics should also foster greater interactions with industry, academia, government, etc., to enhance the drug development process.

The ad hoc Subcommittee on Experimental Therapeutics will also advise on policies, procedures, and programs to optimize strategies in the pre-clinical discovery and development of novel anticancer therapeutic interventions to address the critical translational support needs of the extramural community.



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