

## NCI Patient Advocate Steering Committee (PASC)

Below is a list of the acronyms mentioned on the July 9, 2012 PASC call regarding drug development at NCI. Also included is an informal description of each.

---

<b>Acronym</b>	<b>Definition</b>
BRB	<u>Biological Resources Branch</u> – branch within DTP that supports preclinical and early clinical studies of biological response modifiers research. Also oversees the operation of a pilot multi-product cGMP facility located on the NCI-Frederick campus.
CBC	<u>Chemical Biology Consortium</u> – the early discovery part of the NEXt Program that consists of a group of specialized scientific centers focusing on target development and drug discovery.
CDA	<u>Confidential Disclosure Agreement</u> – a document used between the NIH and an outside party that defines the terms and basic criteria used to assure that the party receiving confidential information will maintain the information in confidentiality and will not use the confidential information for any purpose other than described in the CDA.
CDP	<u>Cancer Diagnosis Program</u> – program within DCTD that stimulates, coordinates, and funds specimen resources, databases related to those specimens, and research on diagnostic and improved technologies to better characterize tumors.
CSA	<u>Clinical Supply Agreement</u> – used for distribution of commercial agents in support of high priority phase 3 trials.
CIB	<u>Clinical Investigations Branch</u> – branch within CTEP, DCTD that is responsible for scientific oversight and coordination of large, multicenter clinical trials exploring innovative disease therapeutics and biomarkers. CIB also liaises with NCI Cooperative Groups and Scientific Steering Committees.
CRADA	<u>Cooperative Research and Development Agreement</u> – a commonly used agreement with collaborators, one of the few mechanisms that allow the NCI to bring in outside funding and the only mechanism by which we can guarantee licensing rights to commercial partners.
CTA	<u>Clinical Trial Agreement</u> – a commonly used agreement with collaborators of more limited scope than a CRADA, usually focused solely on clinical studies.
CTEP	<u>Cancer Therapy Evaluation Program</u> – program within DCTD that functions as NCI's primary clinical evaluator of new anticancer agents, radiation treatments, and surgical methods. The program also administers the 11 cooperative research groups and provides and tracks experimental agents for clinical trials run by other NCI components.
DCTD	<u>Division of Cancer Treatment and Diagnosis</u> – the Division at NCI that supports the translation of promising research areas into improved diagnostic and therapeutic treatments for cancer patients. Encompasses eight major programs: 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), Biometrics Research Branch (BRB), and Office of Cancer Complementary and Alternative Medicine (OCCAM).

DTP	<u>Developmental Therapeutics Program</u> – program within DCTD that serves as a vital resource to facilitate discovery and late-stage preclinical development.
IDB	<u>Investigational Drug Branch</u> – implements and oversees an innovative investigational experimental therapeutics program. IDB collaborates with academia and industry through a unique contract and grant NCI funded program to carry out the clinical evaluation of novel anti-cancer agents.
IDSC	<u>Investigational Drug Steering Committee</u> – created at the recommendation of the NCI’s Clinical Trials Working Group report to assist with the design and prioritization of early phase drug development trials with agents for which CTEP holds an IND.
IND	<u>Investigational New Drug</u> – an investigational drug is one that is under study but does not have permission from the U.S. Food and Drug Administration (FDA) to be legally marketed and sold in the United States. If laboratory results for the new drug are promising, the drug company or sponsor must apply for FDA approval to test the drug in people. This is called an IND application. Once the IND application is approved, clinical trials can begin.
MOU	<u>Memorandum of Understanding</u> – a document describing a bilateral or multilateral agreement between parties.
MTA	<u>Materials Transfer Agreement</u> – simple agreement (relatively) to cover the transfer of materials between entities.
NERF	<u>Non-Exclusive Royalty Free (License)</u> – a license that gives Collaborators “freedom to operate”, they do not have to pay a royalty for use of this license.
NExT	<u>NCI Experimental Therapeutics Program</u> – the single pipeline drug discovery program administered by DCTD. NExT consolidates NCI’s anticancer drug discovery and development resources in support of a robust, balanced, goal-driven therapeutics pipeline. Combined, these resources are capable of supporting a discovery and development continuum from initial discovery through Phase II clinical trial evaluation.
NME	<u>New Molecular Entity</u> – new and innovative chemical structures never used before in clinical practice. Such novel new drugs are often called NMEs.
RAB	<u>Regulatory Affairs Branch</u> – provides IND support and acts as liaison to the FDA for CTEP, DCTD. RAB also fosters pharmaceutical collaboration in evaluating new anti-cancer agents, through the implementation of appropriate agreements.
RAID	<u>Rapid Access to Intervention Development</u> – DCTD program that provides IND-enabling studies to select academic collaborators.
SAC	<u>Senior Advisory Committee</u> – internal NCI committee consisting of Division and program Directors responsible for resourcing decisions for NExT projects.
SEP	<u>Special Emphasis Panel</u> – Federal Advisory Committee Act (FACA) approved committee of external participants that provide information and prioritization to internal committees for NExT project.