Developmental Therapeutics Clinic

Early Phase Clinical Trials Program

Division of Cancer Treatment and Diagnosis (DCTD)

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NIH NATIONAL CANCER INSTITUTE

July 12th, 2019

Developmental Therapeutics Clinic (DTC)

- DTC is part of of the Division of Cancer Treatment and Diagnosis, tasked with early drug development of novel agents, particularly in the exploration and confirmation of mechanism of action.

- DTC conducts early-phase trials of novel agents with correlative pharmacokinetic and pharmacodynamic endpoints

- The DTC works in concert with NCI's Experimental Therapeutics Program (NExT)
  - Drug discovery and development initiative

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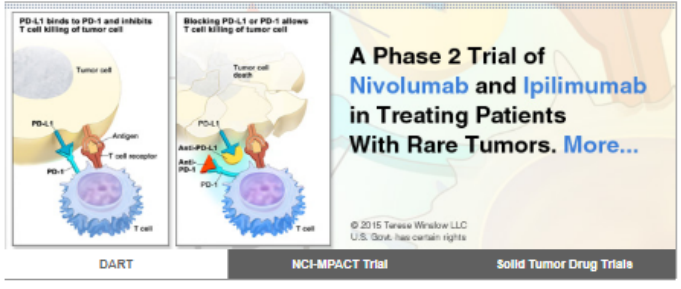
DCTD Division of Cancer Treatment & Diagnosis
CCR Center for Cancer Research

DTC Developmental Therapeutics Clinic



Welcome to the Developmental Therapeutics Clinic

The goal of the National Cancer Institute (NCI) Developmental Therapeutics Clinic (DTC) is to develop new treatments for patients with advanced cancer through innovative early-phase clinical trials. This clinic focuses on rationally developing new drugs and drug combinations that target specific abnormalities in tumors, rather than on one cancer type or histology. DTC staff utilize the power of molecular, precision medicine to design clinical trials that can help evaluate the benefit of the proposed therapy. DTC is part of the NCI, which is one of 27 institutes and centers that comprise the National Institutes of Health (NIH). DTC participates in the Experimental Therapeutics Clinical Trials Network (ETCTN) and supports the work of the Division of Cancer Treatment and Diagnosis (DCTD).

Each year, patients from around the world with cancers that have relapsed after standard treatment visit DTC for consultation about participation in the innovative new treatment trials conducted at NIH. DTC treats patients in the NIH Clinical Center, and DTC staff collaborate with the patient's current clinical provider to ensure outstanding clinical care. Our patients are referred by other patients, patient's physicians, families and friends, or personally may seek out these studies independently.

If you are a referring physician, patient, or family member, please contact us by email or phone.

Clinical Trials Questions?
Speak with a DTC Patient Coordinator

General Cancer Questions?
Speak with NCI's Cancer Information Service

Tweets by @NCItreatment

NCI Treatment Retweeted
NCI Prevention @NCIprevention
FUNDING OPPORTUNITY
Oncology Co-Clinical Imaging Research Resources to Encourage Consensus on Quantitative Imaging Methods and Precision Medicine (U24 - Clinical Trial Optional) buff.ly/2UGNZUu

Embed View on Twitter

News

DTC Offers Fellowship Opportunities

Arjun Mittra, MD, DTC Advanced Fellow, Receives Conquer Cancer Foundation 2019 ASCO Annual Meeting Merit Award

Three DTC Staff Presentations at AACR 2019:

– Phase I Trial of Recombinant Human Interleukin 15 (rhIL-15) in Combination with Nivolumab and Ipilimumab in Refractory Cancers

– DNA Damage Response and Therapeutic Activity following Once-daily Administration of the Wee 1 Inhibitor AZD1775 (adavosertib)

– A Phase II Trial of TRC102 (methoxyamine HCl) in Combination with Temozolomide in Patients with Relapsed

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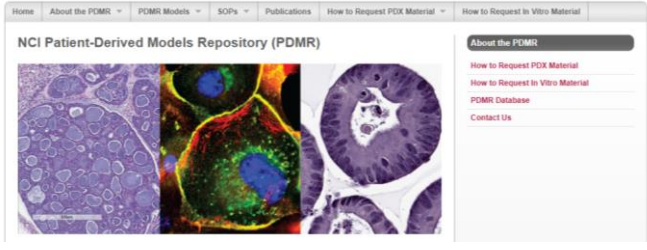
PDMR NCI Patient-Derived Models Repository
An NCI Precision Oncology Initiative℠ Resource



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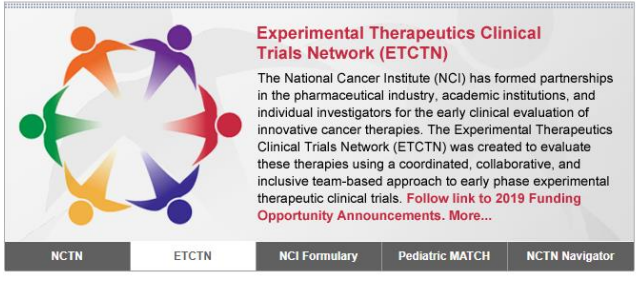
CTEP Cancer Therapy Evaluation Program



DTC Developmental Therapeutics Clinic

Clinical Trials List
Clinical Trials Q&A
Clinical Trials Contacts

Clinical Trials

Last Updated: 05/09/19

Clinical Trials List

These are the trials that are currently offered at our clinic.

Tumor Type

- ▶ All Cancer Types
- ▶ Sarcoma
- ▶ Lymphoma
- ▶ MDS
- ▶ Rare Tumors

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Trial Type

- ▶ Immunotherapy
- ▶ Precision Medicine

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Trial Phase

- ▶ Phase 1
- ▶ Phase 2

Clinical Trials Questions?

Speak with a DTC Patient Coordinator

General Cancer Questions?

Speak with NCI's Cancer Information Service

▼ MDS

- Phase I Trial of the Combination of Bortezomib and Clofarabine in Adults with Refractory Solid Tumors

DTC Trials: Planned MDS cohort inclusion for Aza-TdC

- Nucleoside analog 5-aza-4’-thio-2’-deoxycytidine
- DNA methyltransferase 1 (DNMT1) inhibitor

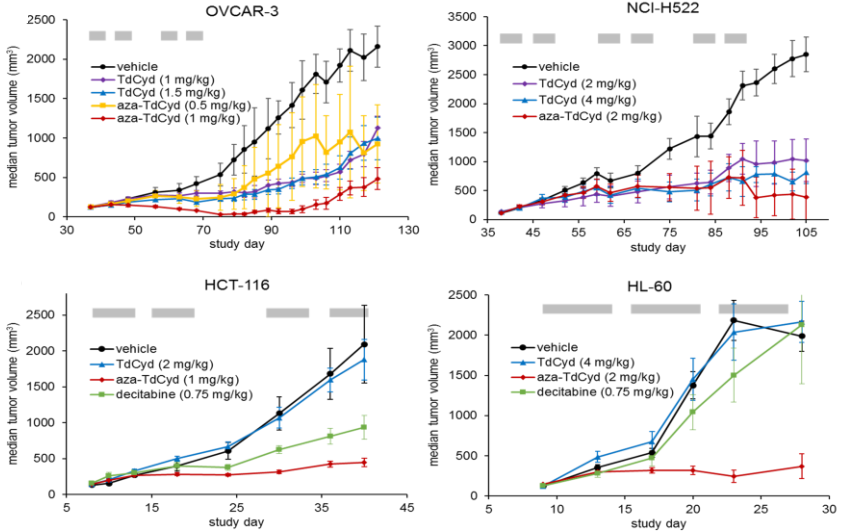
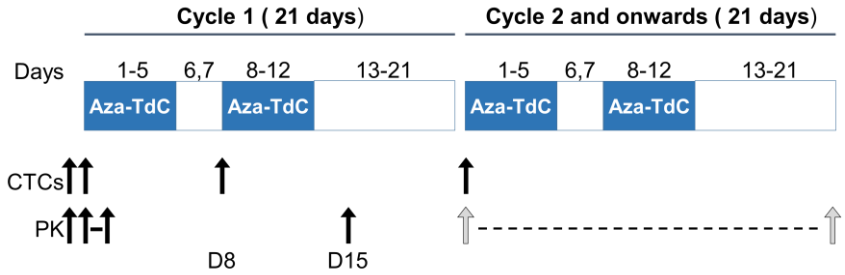


Figure 1. Efficacy of Aza-TdC (aza-TdCyd) and TdCyd in human tumor xenograft models.



Study Objectives:

- Safety, tolerability, and maximum tolerated dose (MTD) of oral Aza-TdC administered daily for 5 days a week for 2 weeks, with one week off, in 21-day cycles, to patients with refractory solid tumors
- Determine the pharmacokinetics, pharmacodynamics (gene re-expression) and preliminary activity of oral Aza-TdC

Dose Level	Aza-TdC, mg
-1	1
1	2
2	4
3	8
4	16
5	32
6	64
7	128

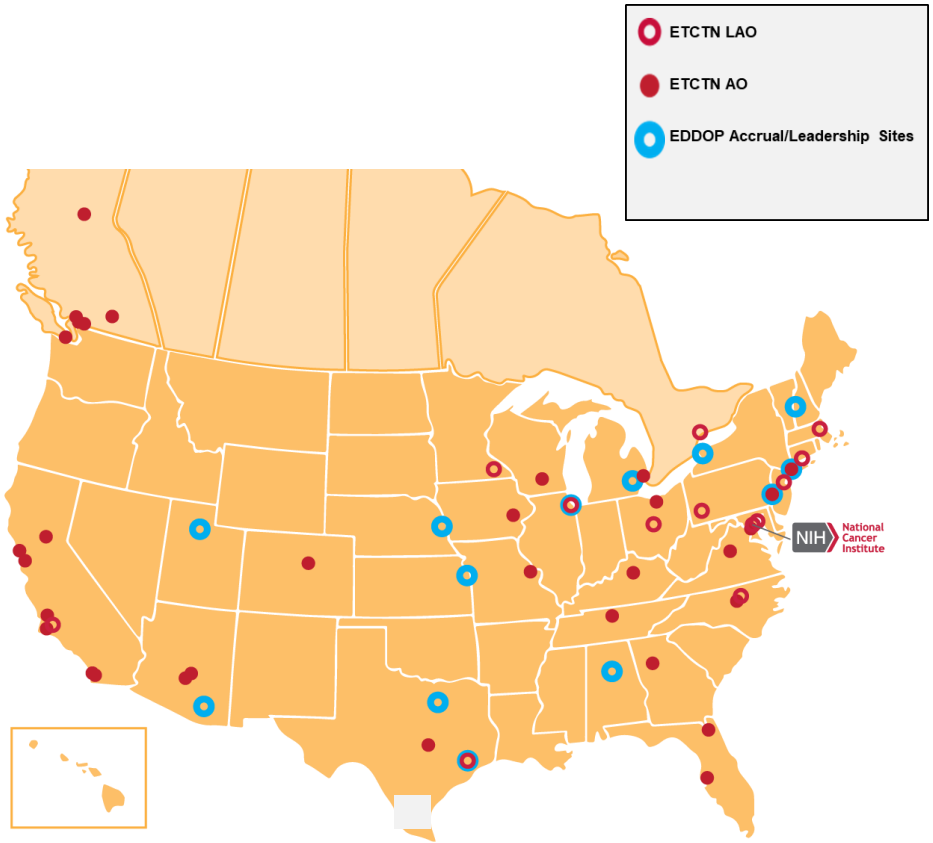
Experimental Therapeutics Clinical Trials Network

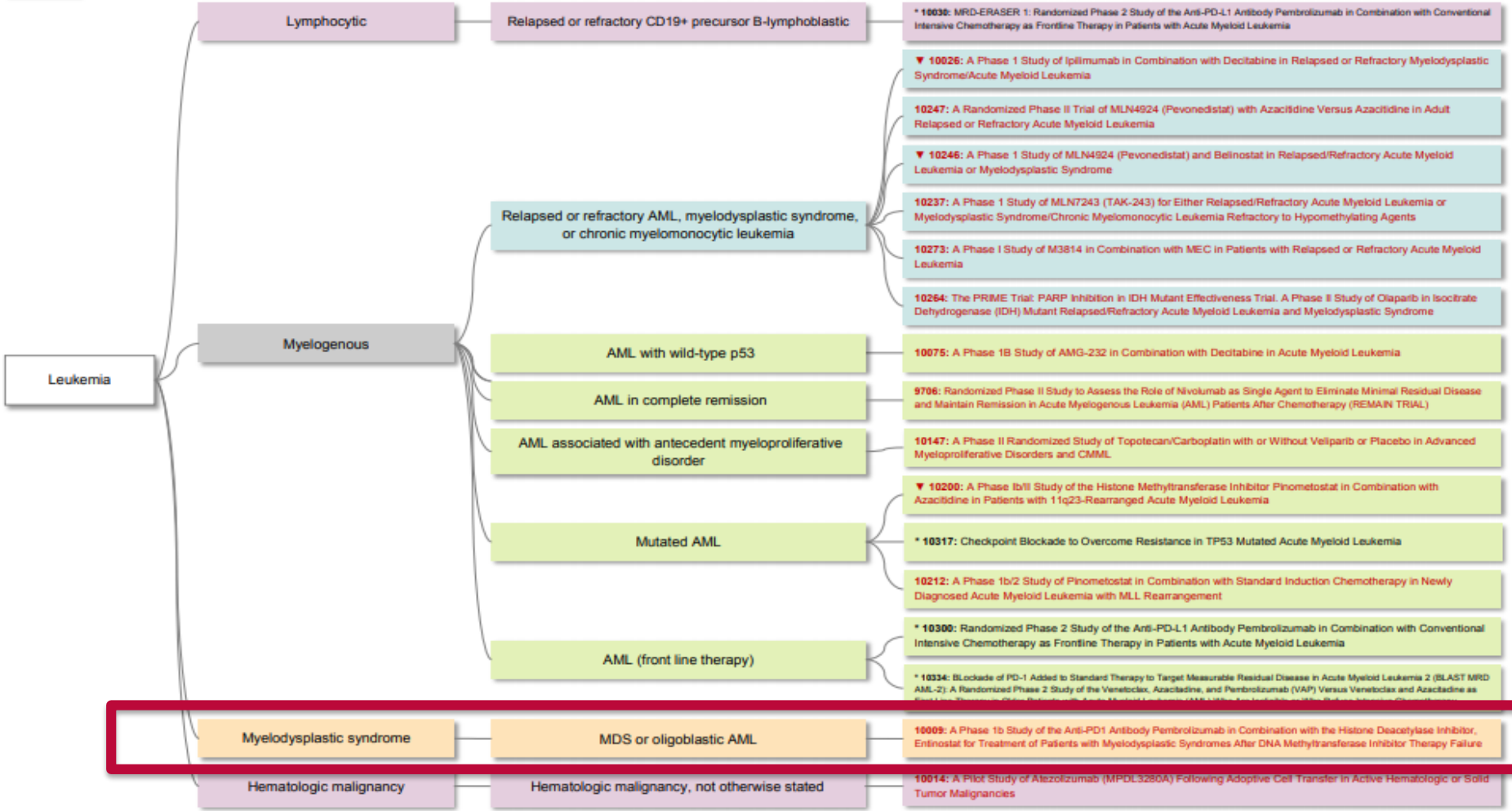
Experimental Therapeutics Clinical Trials Network (ETCTN)

- The National Cancer Institute (NCI) has formed partnerships in the pharmaceutical industry, academic institutions, and individual investigators for the early clinical evaluation of innovative cancer therapies.
- The ETCTN was created to evaluate these therapies using a coordinated, collaborative, and inclusive team-based approach to early phase experimental therapeutic clinical trials.
    - Collaborative approach
    - Reproducible translational science
    - Not only for solid tumors: network of hematological malignancy trials

ETCTN: Lead Academic (12) and Affiliated Organizations (41)

- Clinical sites participate in a **Phase 1 Program** supported by UM1 grants
- **Phase 2 Program** is supported by cooperative agreements as supplements to the existing phase 1 UM1 grants
- Conduct early clinical trials of NCI-IND agents in high priority areas of unmet medical needs
- Integrate preclinical findings using clinical samples for biomarker analysis
- Promote collaboration among institutions and investigators





NOTE: * No ClinicalTrials.gov webpage is available at this time (typically for approved LOIs or protocols in review); ▼ Limited trial; not open ETCTN-wide; Version Date: June 12, 2019

ETCTN-MDS

NIH U.S. National Library of Medicine
ClinicalTrials.gov

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Home > Search Results > Study Record Detail

Save this study

Entinostat and Pembrolizumab in Treating Patients With Myelodysplastic Syndrome After DNMTi Therapy Failure

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT02936752

Recruitment Status : Recruiting
First Posted : October 18, 2016
Last Update Posted : June 6, 2019

See Contacts and Locations

Sponsor:
National Cancer Institute (NCI)

Information provided by (Responsible Party):
National Cancer Institute (NCI)

Open at multiple sites

PDMR

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PDMR NCI Patient-Derived Models Repository
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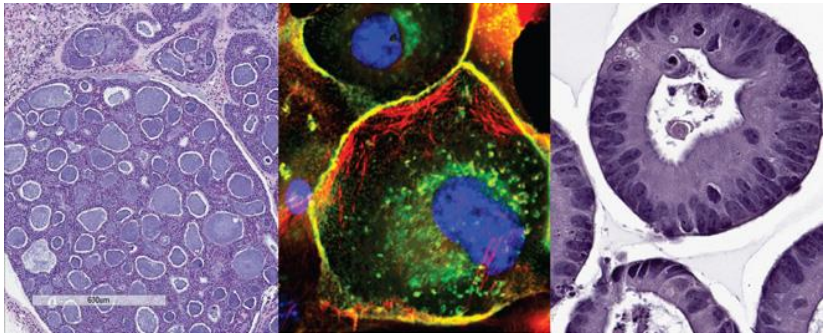

https://pdmr.cancer.gov/

- Patient-derived xenografts (PDXs), in vitro patient-derived tumor cell cultures (PDCs) and cancer associated fibroblasts (CAFs) as well as patient-derived organoids (PDOrg)
- Clinically-annotated with molecular information available in an easily accessible database
- Develop models allowing comparative assessment of molecular predictors of drug efficacy.
- Establish predictive genomic signatures and/or proof of mechanism pharmacodynamics
- Available to the extramural community

Opportunities

- Current and upcoming trial options for MDS patients
  - Clofarabine+bortezomib
  - Aza-TdC
- DTC participates within ETCTN: trials within this network are available to our clinic
- High priority area for DTC

http://dtc.cancer.gov

www.cancer.gov

www.cancer.gov/espanol