

CTEP Young Investigator Meeting

Pamela Harris, M.D.

Percy Ivy, M.D.

James A. Zwiebel, M.D.

Investigational Drug Branch

Cancer Therapy Evaluation Program, NCI

Patricia LoRusso, D.O.

Karmanos Cancer Institute

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Today's Agenda

- CTEP overview & the Career Development LOI, *James Zwiebel, MD*
- The CTEP ETCTN, *Percy Ivy, MD*
- LOI basics from a PI's perspective, *Patricia LoRusso, DO*
- Elective rotation at CTEP for fellows and faculty, *Pamela Harris, MD*

The CTEP Mission

To improve the lives of cancer patients by finding better ways to treat, control and cure cancer.

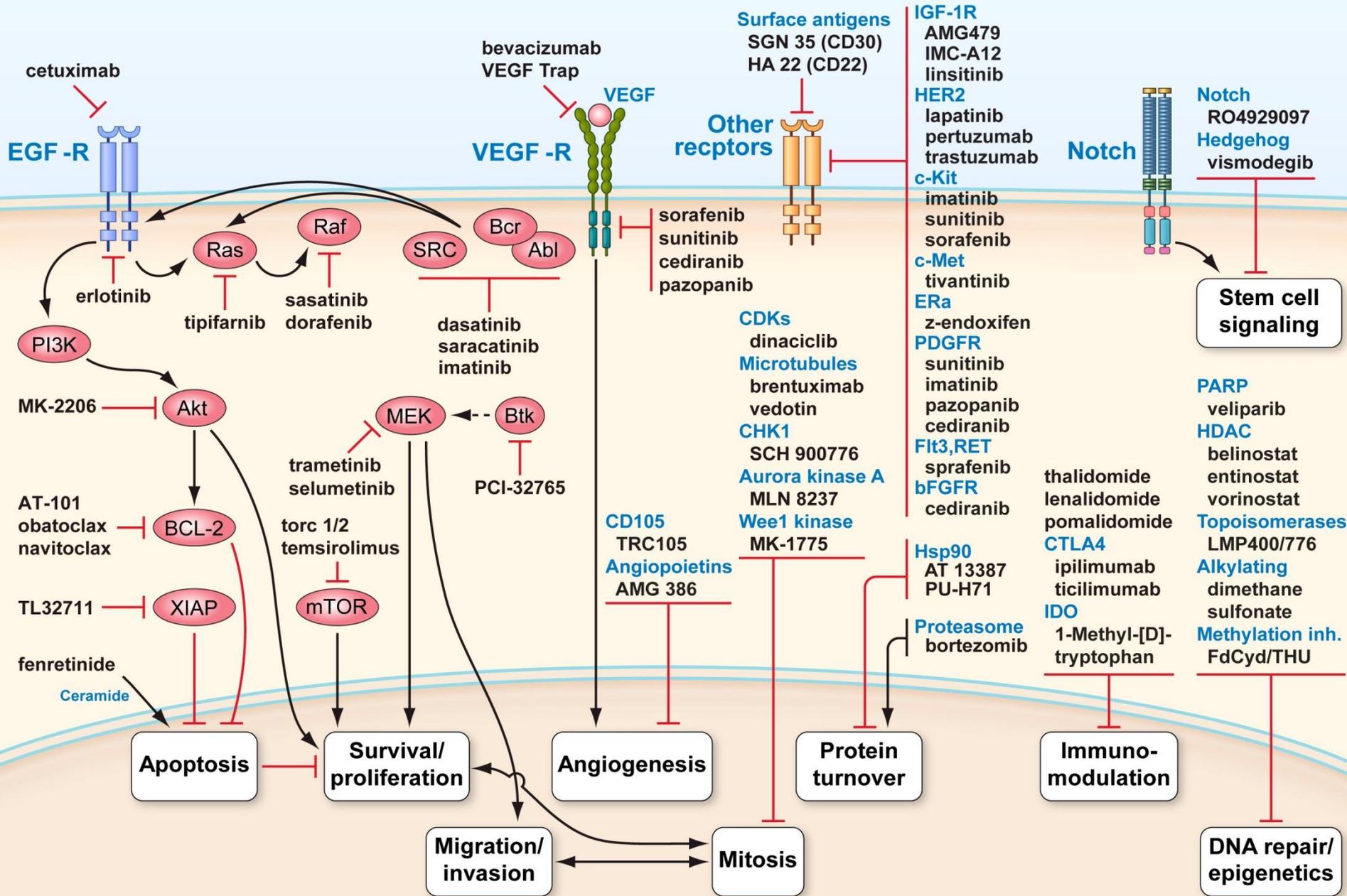
CTEP's Role in Drug Development

- Combinations of targeted agents a high priority
 - More than 100 trials initiated since 2000
 - Facilitated by the IP language in CTEP-industry agreements
- Mechanism of Action/Proof of Principle/Biomarkers
- Broaden development in relevant tumor types
 - Industry focus on limited number of indications dictated by market considerations

Source of CTEP Agents

- Agents come through the NCI Experimental Therapeutics Program (NExT) review:
 - Industry
 - Academia
 - NCI's Chemical Biology Consortium

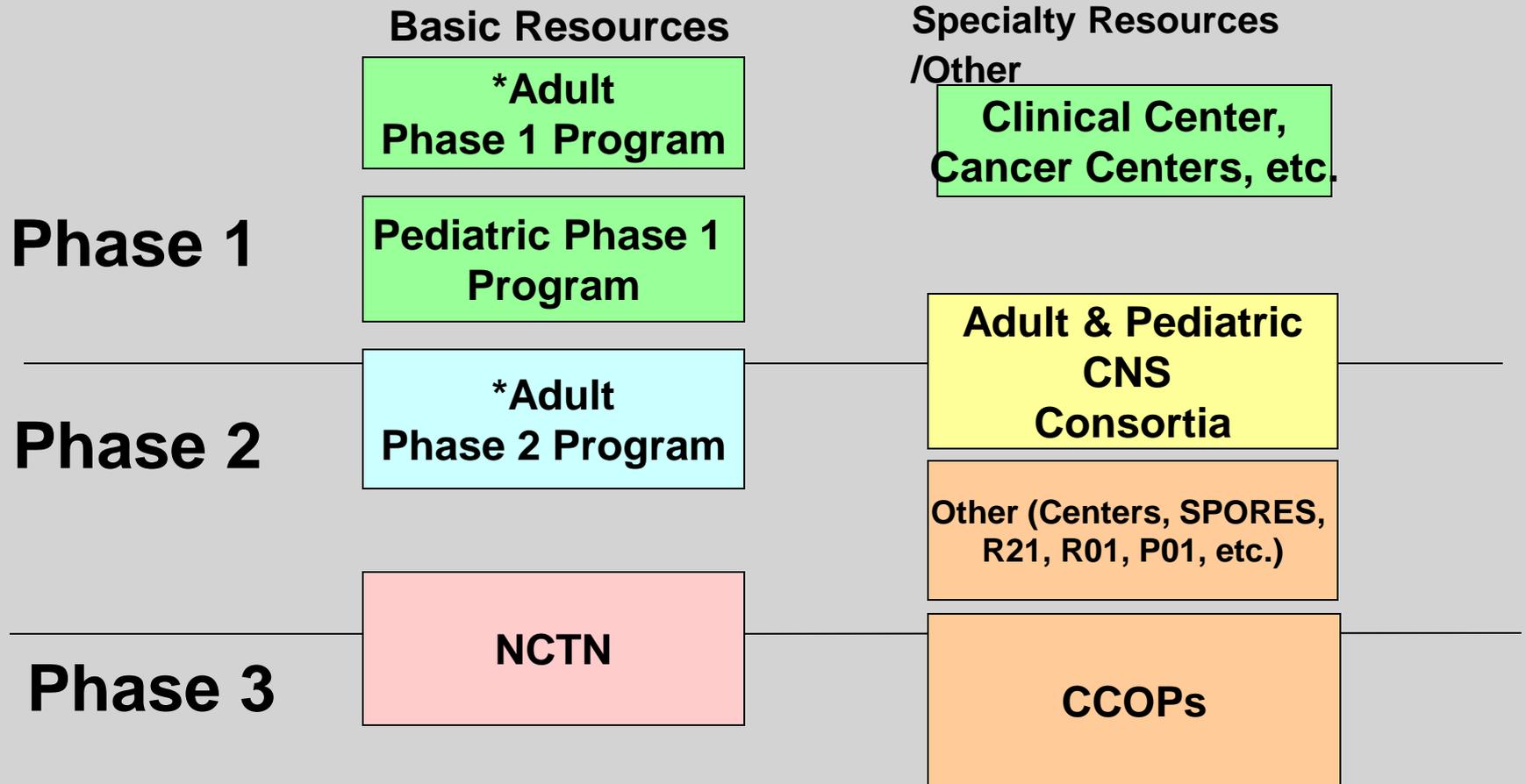
High Priority Targets and Agents



CTEP by Numbers

- Currently sponsors over 100 INDs; >10 new INDs filed each year
- Approx. 11,000 registered investigators at over 3,300 institutions
- Over 750 active protocols
- 150-250 new protocols/year
- 20,000 patients accrued/year
- Over 80 collaborative agreements with pharmaceutical companies

CTEP Clinical Trials Networks



*CTEP ETCTN

How is the System Evolving?

- ***Team Science*** focused approach for investigational agent development:
 - Project teams will identify and address important questions
- ***Molecular profiling*** of patient tumors
- ***Enhanced collaboration and integration*** with NCI-sponsored programs, including SPORES, Centers, mouse models consortia, grantees (R01s, P01s)

Operational Efficiency Working Group (OEWG), 2010

Provided recommendations to the NCI on strategies to decrease the time required to activate NCI-sponsored clinical trials

OEWG Timelines

Target timelines and **Absolute deadlines** were created for studies to go from Concept/LOI submission to activation (activation defined as study open to patient enrollment):

➤ Phase 1 and 2 Studies:

- Target Timeline – 210 days
- Absolute Deadline – ~~540 days~~ **Now 450 days**

➤ Phase 3 Studies:

- Target Timeline – 300 days
- Absolute Deadline – ~~730 days~~ **Now 540 days**

Implementation of OEWG recommendations

- **Project Managers** to closely track study timelines
- **Secure website** to allow investigators, operations staff, and NCI staff to monitor timelines
- Routine **conference calls** between NCI reviewers and external investigators to quickly resolve issues and decrease the need for multiple document revisions
- **Medical Editors** to compile Consensus Reviews and to insert applicable revisions directly into the Protocol document using Track Changes[®], thus saving investigators valuable time

CANCER THERAPY EVALUATION PROGRAM

Jeffrey Abrams, MD

Operations & Informatics Branch

Steve Friedman, MHSA

**Clinical
Grants
and
Contracts
Branch**
**Roy Wu,
PhD**

**Clinical
Investigations
Branch**
**Meg Mooney,
MD**

**Regulatory
Affairs
Branch**
**Jan
Casadei,
PhD**

**Investigational
Drug Branch**
**James Zwiebel,
MD**

**Pharmaceutical
Management
Branch**
**Charles Hall,
Jr., RPh, MBA**

**Clinical
Trials
Monitoring
Branch**
**Gary
Smith, MT,
MGA**

Investigational Drug Branch

James Zwiebel, MD, Chief

Sections

Investigational Therapeutics 1

(Angiogenesis, embryonic pathways, apoptosis, cell death)

Percy Ivy, MD
Associate Branch Chief

Investigational Therapeutics 2

(PI3K/AKT/mTOR, cell cycle, microtubules, proteosomes, DNA repair)

John Wright, MD PhD
Associate Branch Chief

Investigational Therapeutics 3

(Angiogenesis, EGFR, MAPK pathway, imids, immunotherapy, ADCs, epigenetics)

Helen Chen, MD
Associate Branch Chief

Pamela Harris, MD

Alice Chen, MD

Jeffrey Moscow, MD

Naoko Takebe, MD PhD

Austin Doyle, MD

Elad Sharon, MD, MPH

Richard Piekarz, MD PhD Howard Streicher, MD



National Cancer Institute

CTEP Career Development LOI Program

Career Development LOI

Goal: To facilitate career development in translational cancer research

Prioritization of solicited LOIs

- To provide junior faculty with a *competitive advantage* within the LOI review process:
 - Award study to young investigator whose proposal is of similar quality as LOIs submitted by more senior, established investigators

Mentorship and institutional support

- Identify senior **faculty mentor**
- Obtain **institutional commitment** for:
 - Research nursing support
 - Data management and statistical support
 - Access to patients
- Prioritization of LOIs from young investigators may provide an incentive for institutional support

Submission requirements - 1

- Study proposals utilizing a CTEP-held IND agent and meeting the CTEP LOI evaluation criteria
- Junior faculty within 7 years of completion of training
- A major interest in clinical research and the intention to develop a career in that field
- Institutional track record in carrying out trials with investigational agents

Submission requirements - 2

- Letters of Commitment:
 - Institution:
 - Support for the proposed study, e.g., research nursing staff, data monitoring, etc.
 - Senior faculty member who will serve as a mentor:
 - provide expertise and oversight in the design and conduct of the trial
 - confirm the feasibility of the proposed trial within the institutional setting
 - make every reasonable effort to enable the PI to be able to conduct clinical trial successfully

CTEP Cancer Therapy Evaluation Program

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- Home
- Investigator Resources
- Protocol Development
- Industry Collaborations
- Initiatives / Collaborations
- More Links
- About CTEP
- Secure Access



MAJOR INITIATIVES:



Michaele C. Christian Oncology Development Lectureship and Award

This award was established by the Cancer Therapy Evaluation Program in 2007 to honor the twenty year NCI career of Michaele C. Christian. Dr. Christian was appointed Associate Director of the Cancer Therapy Evaluation Program of DCTD in 1997 after serving as head of the Investigational Drug Branch overseeing the clinical development of novel anticancer agents. [More...](#)

SPOTLIGHT ON:



The Investigational Drug Steering Committee

In June 2005, the Clinical Trials Working Group, a broadly constituted panel with experts from academic research institutions, community oncology practices, the pharmaceutical and biotechnology industries, [More...](#)

MESSAGE FROM THE CTEP ASSOCIATE DIRECTOR:



CTEP is responsible, within DCTD, for coordinating the largest, publicly funded oncology clinical trials organization in the world. With over 900 active trials enrolling annually 30,000 study participants, [More...](#)

CTEP BRANCHES AND OFFICES

OAD

Office of the Associate Director
Plans, evaluates and

IDB

Investigational Drug Branch
Implements and oversees an innovative investigational experimental therapeutics

CTEP HIGHLIGHTS

Joan K. Mauer Memorial Award announced

Information on CTEP

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