



# CTEP/IDB Visiting Physician Externship Program

“A program designed by CTEP to provide both U.S. and foreign fellows and young investigators with intense advanced training in all aspects of drug development, particularly in early drug development”

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# CTEP's Mission

- **The Cancer Therapy Evaluation Program is a branch of the NCI with the explicit goal “To improve the lives of cancer patients by finding better ways to treat, control and cure cancer”**
- **CTEP supports a national program of cancer research by:**
  - 1) Interacting with the Pharmaceutical Industry and NIH researchers to bring interesting new agents to experienced US investigators to conduct trials**
  - 2) encouraging high-quality research which addresses critical clinical questions while seeking to better answer translational questions which inform about molecular targets and mechanisms of drug effects**
  - 3) beginning to develop and run clinical trials using TEAM Science (with clinician scientists, translational scientists and basic scientists)**
  - 3) ensuring the safety of clinical trial subjects**
  - 4) partnering with the FDA**

# **During a Typical Visiting Physician's 1 Month Externship, CTEP Staff will Review:**

- **6 Concepts**
  - **16 LOIs**
  - **21 Protocols**
  - **55 Protocol Revisions**
  - **193 Protocol Amendments**
- (in addition to other activities)**

# Visiting Physicians are:

- Involved in the Investigational Drug Branch's day-to-day activities
- Review, in collaboration with staff, LOIs to conduct trials with CTEP agents
- Present reviews to IDB staff and to the Protocol Review Committee
- Familiarize themselves with the various branches who, with IDB, make the conduct of outstanding trials possible: Clinical Investigation, Clinical Grants and Contracts, Pharmaceutical, Regulatory, Clinical Trials Monitoring, Operations and Informatics, and the Biometrics Division
- Learn the thought processes involved in creating drug development plans
- Learn the critical elements of a good protocol

# Visiting Physicians also:

- Learn how concepts to perform large cooperative group trials are evaluated
- Gain an appreciation of “team science,” i.e. how different disciplines interact to optimize the knowledge which will be gained from clinical trials
- Gain an appreciation for how correlative studies are incorporated into clinical trials
- If desired, work on a research project of his/her choice (examples include using the CTEP database to predict phase 1 DLTs, relationship between age and DLTs, review of CTEP phase 1 experience in small cell lung cancer, review of CTEP phase 1 experience in melanoma, co-author a paper about drugs that target cancer cell metabolism, analysis of ~~hepatotoxicity in phase 1 trials~~)

# Weekly Meetings Which Visiting Physicians Are Encouraged to Attend:

- **Monday- Drug Combination Meeting; Pharmaceutical Company Presentations**
- **Tuesday- Conference Calls with Investigators, Pharma**
- **Wednesday- Investigational Drug Branch LOI Review Meeting; CTEP Program Meetings** (topics of interest in oncology, presentation of drug development plans, etc.); **Review of some phase 2/3 concepts**
- **Thursday- Biomarker Review Committee Meeting; Protocol Review Committee Meeting; monthly meetings with the FDA**
- **Friday- Pharmacodynamic Meeting**
- **Ad Hoc meetings are frequent and varied**

# **In The Words of Recent Participants in The Externship Program**

- **“It has been a phenomenal experience and a rare opportunity!”**
- **“This program has provided me with a foundation that I don’t think I could have obtained anywhere else.”**
- **“My only regret is that I now have to say goodbye to some good friends and wonderful mentors.”**