

## Fox Chase Cancer Center Extramural Research Program

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The Fox Chase Cancer Center Extramural Research Program (ERP) was created to centralize the oncology research efforts of the Fox Chase Network (FCN) and the Oncology Physician Network, Inc. (OPN). OPN is an independent oncology practice association operating in Pennsylvania, and New Jersey. More than 60 academic and private practice medical oncologists participate in this program. OPN has a clinical research program and offers a chemotherapy group-purchasing program. Since its inception in 1999, the clinical research program of OPN has accrued over 300 patients. FCN (described further in separate section) has accrued nearly 5,000 patients to cooperative group treatment studies since its inception in 1986.

In 2005, these groups combined their research infrastructure to facilitate the research process at both the practice OPN and hospital-based FCN level, and to encourage collaborative studies aimed at fighting cancer. It is anticipated this merger will permit the rapid initiation and conduct of investigator-initiated studies at multiple sites. Non-formula fund grant support from the Pennsylvania Tobacco Settlement helped launch the initial steps of consolidating these two research programs. The ERP actively seeks both investigator-initiated studies and industry-sponsored studies focused on detecting, preventing and treating cancer. Institutions that conduct their studies through the ERP gain access to a large patient population, quality-assurance monitoring and single-contract budgeting process.

The effort to combine the research programs and form the ERP was completed near the end of 2005. Primarily, all research projects during 2005 were conducted through OPN. In 2005, OPN enrolled 61 patients to clinical trials. A listing and more detailed description of the 2 highest accruing OPN studies during 2005 as well as other/planned studies initiating through the ERP follows below.

### **Longitudinal enumeration of circulating tumor cells in patients with metastatic colorectal carcinomas.** S. Cohen, in collaboration with Meropol<sup>§</sup>

Although the existence of circulating tumor cells (CTC) has been known for decades, recent advances in immunomagnetic separation technology allow the isolation of these CTC and their characterization. This prospective study enrolls patients with metastatic colorectal cancer beginning their first, second, or third-line systemic therapy and obtains peripheral blood for CTC

enumeration at study entry, 3–4 weeks after initiation, and at subsequent disease evaluation timepoints. The primary endpoint is to evaluate whether change in CTC number can predict clinical outcome. A relationship between CTC and clinical outcome in breast cancer was demonstrated previously. The current study builds upon a pilot study conducted at Fox Chase demonstrating that CTC could be isolated and enumerated from patients with colorectal cancer. Twenty-three patients have been enrolled to this study at Fox Chase and an additional 11 at ERP

practices, making Fox Chase and the ERP one of the leading national accruals.

**A phase II study of paclitaxel, carboplatin and cetuximab as first line treatment for patients with advanced non-small cell lung cancer.**

Langer, in collaboration with Treat<sup>8</sup>

This study is testing the hypothesis that inhibition of the epidermal growth factor receptor with the monoclonal antibody cetuximab will provide additional clinical benefit when given with standard chemotherapy for advanced non-small cell lung cancer. The primary endpoint is response rate, with clinical benefit, time to progression, and overall survival secondary endpoints. To date, out of the 37 patients enrolled (accrual goal of 53), 22 patients have been enrolled at Fox Chase and 13 at OPN practices. This study is expected to achieve its accrual earlier than the projected 18-month goal.

**Investigator-initiated clinical trials development process.** S. Cohen

When an investigator-initiated concept for a clinical trial is first identified, the concept is presented at the Extramural Research Committee, which evaluates each concept for scientific merit and feasibility. This research review com-

mittee contains FCCC investigators, members at affiliated hospitals as well as practices through OPN. If approved, a study concept can proceed to the development of a formal protocol and IRB review at each participating site, with the ERP assuming the role of sponsor and coordinating logistical and regulatory requirements. The ERP works with investigators to write a final protocol, consent form, HIPAA consent and develop case report forms. The ERP conducts study initiation meetings, oversees regulatory processes of the study, and conducts 100% auditing of all data collected on the study. Once all data has been collected and all queries resolved, the ERP performs data entry into a database that is used by the investigator and statistician to analyze and publish study findings. Current protocols in development include: a randomized phase II study of chemotherapy and cetuximab with or without bevacizumab in advanced colorectal cancer, a phase II study of targeted therapeutics for elderly or poor performance status patients with advanced non-small cell lung cancer, phase II studies of novel chemotherapy combinations in head and neck cancer and lymphoma, and a randomized study of cetuximab alone or with chemotherapy in advanced bladder cancer.