

The NCI Program for the Assessment of Clinical Cancer Tests (PACCT)

The overall aims of PACCT are:

- \$ to ensure translation of new knowledge about cancer and new technologies to clinical practice
- \$ to develop more informative laboratory tools to help maximize the impact of cancer treatments

The need for PACCT is based on the fact that many decisions for cancer patient management depend on information derived from clinical laboratory tests in addition to that derived from the history and physical examination. The reliability of a clinical laboratory test is defined by its performance characteristics in the context of its intended use. Regardless of the test's specific performance characteristics, the treating physician must have confidence that the decisions based on the test will maximize benefit to the patient and minimize risk. Significant research and development are involved in producing a test that is reliable enough for routine clinical use.

The PACCT has evolved to ensure that development of the next generation of laboratory tests is efficient and effective.

Plans and Progress

- \$ Convene a Strategy Group (SG) to develop criteria for assessing which markers are ready for further development. The initial focus is to identify the most pressing clinical questions in a few sites and to identify the most promising markers/techniques based on an extensive review of the literature.
 - \$ The SG is composed of scientists from academia and NCI and FDA staff. The areas of expertise represented include clinical oncology, pathology, basic cancer biology, diagnostics technology and assay development, clinical trials methodology, and statistics.
 - \$ The SG makes recommendations that range from the need for workshops, additional research or development of special resources to the need for assay standardization or validation by a clinical trial. The SG has developed draft guidelines for publication of marker/assay studies and draft guidelines for marker/assay development. These two documents are being prepared for publication.
- \$ Based on identified needs, a Statistical Consulting Group (SCG) will be formed.
 - \$ Members of the SCG will be chosen based on proposed research projects focused on developing new approaches to efficient study design and on adapting existing statistical approaches to new types of analyses.
 - \$ The SCG will assist investigators in developing study designs.
- \$ Improve access to human specimens.
 - \$ The NCI has created Tissue Expediter program and developed a website to help researchers locate required specimens.

- \$ The Shared Pathology Informatics Network has been funded to develop an internet-based system to identify needed samples that reside in pathology archives around the country.
- \$ Prepare tissue micro-arrays to meet specified research needs:
 - \$ Cooperative Breast Cancer Tissue Resource (CBCTR) breast tissue arrays (<http://www-cbctr.ims.nci.nih.gov/>)
 - \$ Tissue Array Research Program (TARP) (<http://www.cancer.gov/tarp>)
- \$ Make standardized reagents and control materials available.
 - \$ Plans are being made for preparation and supply of probes or antibodies that can be used for comparative studies.
 - \$ Plans are being made for preparation of control materials such as tissue micro-arrays and/or cell lines.
- \$ Support validation studies.
 - \$ Make facilities available where reagents/assays for the same marker can be compared on standard tumor sets.
 - \$ Support quality control studies by interested laboratories.
 - \$ Involve professional organizations with interest in standardization. The NCI has a liaison to the College of American Pathologists Cancer Committee and has established a working group that involves the European Organization for Research and Treatment of Cancer.
 - \$ Support clinical trials to evaluate markers prospectively. The NCI has released Program Announcements for Phased Application Awards in Cancer Prognosis and Prediction (PAR 01-061) & Cancer Prognosis and Prediction: SBIR/STTR Initiative (PAR 01-062)