Multiagency Effort to Focus on PET as Biomarker

On February 14, the National Cancer Institute (NCI), the Food and Drug Administration (FDA), and the Centers for Medicare and Medicaid Services (CMS) announced the formation of the Oncology Biomarker Qualification Initiative (OBQI), an agreement among the 3 agencies to collaborate on improving the development of therapies and outcomes for cancer patients through biomarker development and evaluation. To the surprise of many in research and industry, the first collaborative project will focus not on biologic samples but on the validation and standardization of ^{18}F-FDG PET in the identification and characterization of biochemical changes in cancer. Details of the mechanisms by which this research will be funded and completed were not included in the original agreement announcement, although insiders point to initial funding of PET assessments of radioimmunotherapy in patients with non-Hodgkin's lymphoma.

The OBQI is the first time the 3 U.S. Department of Health and Human Services (HHS) agencies have focused together on biomarkers as a way to accelerate the development and evaluation of cancer therapies. "We are excited about this effort to speed the development and delivery of new cancer treatments for patients," said HHS Secretary Mike Leavitt. "By bringing together the scientific, regulatory, and delivery expertise of these 3 agencies, we can bring targeted, more personalized cancer diagnostics, treatments, and preventions to patients more rapidly."

Under the OBQI, biomarker research will focus on: (1) standardizing and evaluating imaging technologies to assess treatments; (2) developing scientific bases for diagnostic assays to enable personalized therapeutic approaches; (3) instituting new trial designs to utilize biomarkers; and (4) aggregating trial data in an accessible format to ensure that key findings are shared. A joint press release accompanying the announcement indicated that OBQI will address questions about ways in which specific biomarkers can be used to:

- Provide early assessments of response to treatment;
- Determine more definitively whether apoptosis is occurring, regardless of tumor size;
- Identify which patients are at high risk of recurrence after therapy;
- Predict response in specific patients to specific therapies; and
- Efficiently and effectively evaluate investigational therapies.

The FDA and NCI formed an Interagency Oncology Task Force (IOTF) in 2003 that served as the source for the current interagency Memorandum of Understanding, which, among its goals includes "standardization of approaches for evaluating biomarkers and tools in diagnosing, staging, and assessing therapeutic response in cancer clinical trials." The agencies have agreed to "collaborate through working groups and steering committees to develop strategic plans, set priorities, and leverage resources and expertise from multiple sources, including the private sector, toward the goal of improving the clinical utility of biomarker technologies as diagnostic and assessment tools that facilitate the development of safer and more effective cancer therapies."

"By identifying biomarkers for specific cancers and clinically evaluating them, researchers will have an evidence base for their use in targeted drug development and to determine which therapies are likely to work for patients before treatment selection," said NCI Deputy Director and Deputy Director for Advanced Technologies and Strategic Scientific Initiatives Dr. Anna Barker. "Rather than waiting weeks to months to determine if a specific drug works for a patient, biomarkers could be used to monitor real-time treatment responses."

The OBQI team will design a number of initiatives to identify and clinically qualify other cancer biomarkers in 2006 and 2007, and these and the PET imaging initiative will be funded as separate projects through the participating agencies. It is anticipated that one of the participating agencies will host a central OBQI Web site through which news of the individual initiatives can be accessed. Language included in the initial press release indicated that the OBQI will bring together scientists already at work on FDA Critical Path and NIH Roadmap Initiatives and will also represent the work of the NCI/FDA IOTF.

The full text of the interagency Memorandum of Understanding is available at www.fda.gov/oc/mous/domestic/FDA-NCI-CMS.html. Newsline will follow closely upcoming announcements of specific programs and requests for funding applications related to this initiative.