Review of Oncology Studies Funded by the FDA Office of Women’s Health – 1994-2007
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Background: The FDA Office of Women's Health (OWH) funds studies to assess women's participation in clinical trials submitted to FDA and to understand sex differences in disease development, detection, prevention and outcomes. This project assesses the impact of OWH funded oncology studies.

Methods: The final reports were reviewed and grouped as 1. Molecular Mechanism of Treatment Associated Toxicities (MMTAT), 2. Molecular Mechanism of Tumor Development and Suppression (MMTDS), 3. Demographics (DEM), 4. Detection/Prevention (D/P), and 5. Data Analysis (DA).

Results: Of 29 oncology studies 19 were completed.

- **MMTAT (9):** Five studies investigated tamoxifen toxicities and supported the black box warning of “serious and life-threatening uterine malignancies” in labeling that was added in 2002. Others studied 1) sex differences in transporter genes linked to tolerability and toxicity, 2) co-administration of anti-HER2 antibody with doxorubicin to show that cardiotoxicity in rats did not intensify, 3) genotoxic and carcinogenic activities of soy isoflavones, and 4) myelosuppression of progenitor stem cells to alkylating agents.

- **MMTDS (4):** Two studies identified possible mediators in tumor necrosis and their effects on lymphoma tumor growth in mice, one study assessed carcinogenicity of breast implants and one study utilized photo-carcinogenicity testing in mice to determine threshold level of solar similar light.

- **DEM (2):** One study developed a food consumption frequency questionnaire to identify modifiable risk factors in consumption of culture-specific food by African-American women. The other study established a link between low mammography rates and low household income levels.

- **D/P (2):** Two studies explored how to improve detection of breast cancer tumors and tumor progression, the economic benefits of mammography regulation and procedures to monitor chemotherapy treatment response.

- **DA (n=2):** These studies provided alternative statistical analysis methods and survival models to improve the outcomes of research studies, data collection and analytical methods.

Conclusions: The funded oncology studies contributed to the understanding of treatment toxicities, tumor development and detection/prevention of cancer in women.