## Head and Neck Squamous Cell Cancer and the Human Papillomavirus

## **Clinical Trials Planning Meeting (CTPM) November 2008**

## Abstract of meeting available at

## http://www3.interscience.wiley.com/journal/122611421/abstract

This November 2008 Clinical Trials Planning Meeting focused on human papillomavirus (HPV) positive head and neck squamous cell carcinomas, which have primarily been identified in the oropharynx. Discussion began with how the epidemiology and risk factors for this recently identified emerging subset of head and neck cancers differ from other head and neck cancers. There is significant and informative experience with the putative causative agent, HPV, in uterine cervical pre-malignant and malignant lesions. While understanding of oral HPV infection is not as well elucidated as cervical HPV infection, the natural history at the two sites appears to differ, including association with somewhat different HPV types. Current experience with cervical carcinoma vaccines was presented. The meeting continued with presentations on laboratory diagnosis and biomarkers for HPV-positive head and neck cancers. The ubiquity of oral HPV infection was discussed as well as clinical implications, treatment, and counseling. Current evidence from retrospective subgroup analyses suggests that HPV-positive oropharvngeal cancers respond more favorably to treatment than similar HPV-negative tumors. Breakout panels considered trial designs for HPV-positive head and neck cancer trials. The meeting concluded with goals for the future, including development of HPV-based clinical trials with standardized development of laboratory techniques for HPV testing, as well as further elucidation of the epidemiology of oral HPV disease, how HPV-positive head and neck cancers develop, and screening and prevention strategies.

With respect to future treatment trials the following recommendations were made:

- New clinical trials for patients with oropharyngeal cancer should be stratified by patient's HPV status or separate clinical trial initiatives developed for HPV-positive and HPVnegative oropharyngeal cancers.
- Careful consideration in designing future clinical trials for newly diagnosed HPV-positive oropharyngeal cancer patients should be given to survival endpoints, reduction in treatment related morbidity, and differences in outcomes amongst patients. Trial design and accrual expectations need to reflect the incidence and anticipated limited number of recurrences in this subgroup of oropharyngeal cancer patients.
- Current information does not support therapeutic recommendations in the non-research setting based on HPV status.