**Protocol Title:** Randomized Phase II / III Trial of Surgery and Postoperative Radiation Delivered with Concurrent Cisplatin vs. Docetaxel Versus Docetaxel and Cetuximab for High-Risk Squamous Cell Cancer of Head and Neck

**Target Population:** Head and Neck Squamous Cell Carcinoma

**Summary:** This randomized phase II / III trial studies how well radiation therapy works when given together with Cisplatin compared to Docetaxel or Cetuximab and Docetaxel after surgery in treating patients with Stage III-IV Squamous Cell Head and Neck Cancer.

**Key Inclusion Criteria:**
- Pathologically proven diagnosis of Head and Neck Squamous Cell Carcinoma (HNSCC) involving the Oral Cavity (excluding Lips), Oropharynx (p16 Negative), Larynx, or Hypopharynx within 63 Days of registration.
- Patients must have undergone gross total surgical resection of high-risk Oral Cavity, Oropharynx (p16 Negative), Larynx, or Hypopharynx within 63 Days prior to registration.
- Patients must have at least 1 of the following high-risk pathologic features:
  - Extracapsular Nodal Extension
  - Invasive Cancer at the Primary Tumor Resection Margin
- Pathologic Stage III or IV Head and Neck Squamous Cell Carcinoma (HNSCC), including no distant metastases, based upon the following minimum diagnostic workup:
  - General history and physical examination by a radiation oncologist and/or medical oncologist within 84 Days prior to registration.
  - Examination by an Ear, Nose, Throat (ENT) or Head & Neck Surgeon prior to surgery.
    - Intra-operative examination is acceptable documentation.
  - Pre-op Imaging of the Head and Neck:
    - Neck CT (with contrast) or CT / PET (with contrast) and / or an MRI of the Neck (T1 with Gadolinium and T2) within 84 Days prior to surgery
    - Note: Imaging data (diagnostic pre-operative scan showing gross disease) is to be submitted in Digital Imaging and Communications in Medicine (DICOM) format via TRIAD and the report is to be uploaded into Rave.
  - Chest CT Scan (with or without contrast) or CT / PET that includes the Chest (with or without contrast) either within 84 Days prior to surgery or within 120 Days prior to registration.
    - NOTE: If the CT / PET with or without contrast is done within 84 Days prior to surgery, it fulfills the chest imaging requirement.

**Key Exclusion Criteria:**
- Prior Invasive Malignancy (except Non-Melanomatous Skin Cancer) unless disease free for a minimum of 1095 Days (3 Years).
  - Noninvasive Cancers (i.e., Carcinoma in Situ of Breast, Oral Cavity, or Cervix are all permissible) are permitted even if diagnosed and treated < 3 Years ago.
- Patients with simultaneous primaries or bilateral tumors are excluded, with the exception of Bilateral Tonsil Cancers or patients with T1-2, N0, M0 resected differentiated Thyroid Carcinoma, who are eligible.
- Prior systemic chemotherapy or Anti-Epidermal Growth Factor (EGF) therapy for the study cancer.
- Prior radiotherapy to the region of the study cancer that would result in overlap of radiation therapy fields.
- Prior allergic reaction to Cetuximab.

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**For additional information:** [https://clinicaltrials.gov/ct2/show/NCT01810913](https://clinicaltrials.gov/ct2/show/NCT01810913)