RTOG FOUNDATION
3512
(PROBAND-HN)
A Prospective Multicenter Cohort Study of Patients with Newly Diagnosed Head and Neck Cancer
ImClone conceived of LORHAN as a means to establish itself as a leader in head and neck cancer.

Registry seen as a vehicle for engaging thought leaders and community physicians.

Opportunity to understand trends in head and neck cancer and advance medical knowledge.

Led by Medical Affairs group.
## LORHAN vs. Other Registries

<table>
<thead>
<tr>
<th>Selected Registry Features</th>
<th>LORHAN</th>
<th>SEER&lt;sup&gt;1&lt;/sup&gt;</th>
<th>NCDB&lt;sup&gt;2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient baseline characteristics</td>
<td>√</td>
<td>√</td>
<td>√</td>
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<tr>
<td>Detailed data on radiation</td>
<td>√</td>
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<tr>
<td>Detailed data on cancer drugs</td>
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<tr>
<td>Information on supportive care</td>
<td>√</td>
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<tr>
<td>Outcomes by treatment</td>
<td>√</td>
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<td>√</td>
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<tr>
<td>Prospective and longitudinal data</td>
<td>√</td>
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<tr>
<td>Web-based data entry</td>
<td>√</td>
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<tr>
<td>Real-time data access</td>
<td>√</td>
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</tbody>
</table>

<sup>1</sup>Surveillance, Epidemiology and End Results  
<sup>2</sup>National Cancer Data Base
**Study Design**

- Prospective, longitudinal, multicenter observational
- Approximately 100 sites
- 10 years in duration
- Three data collection intervals:

<table>
<thead>
<tr>
<th>Following written IC</th>
<th>Baseline</th>
<th>Initial Treatment</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
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<td>X</td>
<td>X</td>
<td>X</td>
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</table>

Re-treatment information was collected for patients with progressive/recurrent disease or new primaries.
LORHAN Primary Objective

- Describe, in detail, patterns of care of HNC patients
- Hypotheses tested:
  - There is no difference in pattern of care between community and academic settings
  - Results of randomized practice-changing clinical trials will impact the pattern of care in community and academic settings within one year of publication in peer-reviewed journals
LORHAN Secondary Objectives

- Document the outcome (tumor control, survival) by treatment regimen
- Determine the incidence and severity of major dose-limiting and other important treatment toxicities
  - Mucositis/stomatitis, skin reactions, infusion reactions, allergic reactions/hypersensitivity (+neutropenia)
- Identify supportive care received for managing nutrition, pain, nausea and other complications
  - Feeding or tracheotomy tube use, opioid analgesic use, anti-emetic use and use of other selected supportive care agents
Patient Eligibility

- **Inclusion Criteria:**
  - Pathologically (histologically or cytologically) confirmed new diagnosis of carcinoma involving the oral cavity, oropharynx, nasopharynx, hypopharynx, larynx, or neck node metastasis from unknown origin
  - Scheduled to receive radiotherapy and/or drug therapy including chemotherapy, biologic therapy and targeted therapy
  - Written informed consent
  - ≥ 18 years of age

- **Exclusion Criteria:**
  - Registry participation does not exclude participation in clinical trials. Patients scheduled to receive surgery are eligible as long as they are also scheduled to receive medical therapy as described above.
Data Entry

- Web-based CRFs (MedNet Solutions)
  - Most fields had check boxes or drop-down menus
- Data entry by physician or staff
- Encrypted point-to-point data transfer via Secure HTTP protocols
Cumulative Enrollment

Run rate of about 1,000/patients per year
No active promotion
Approximately 100 sites

*As of Sept. 30, 2010
Location of Sites

Patients enrolled in LORHAN, n

*SEER State Cancer Profiles, Oral Cavity & Pharynx, Incidence Rates 2007

NOTE: SEER separates out oral cavity and pharynx cancers from larynx cancers in reporting of head and neck cancers. Oral cavity and pharynx cancers make up the vast majority of head and neck cancers.
# Data Dissemination

## Abstracts (n=12)

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<tr>
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<th>2006</th>
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## Manuscripts (n=5)

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Building on the success of LORHAN

- Demographics
- Detailed Radiation Planning Data
- Detailed Chemo/Systemic Therapy Data
- Survival Outcome, Subsequent Line of Therapy Data
- PRO
- GENOMIC DNA, PDL-1 Expression
RTOG 3512 Steering Committee

• Composed of leading experts in head and neck cancer and representative(s) from the study Sponsor
  – Dr. Stuart Wong (Chair)
  – Dr. Neil Hayes
  – Dr. Amy Chen
  – Dr. Maura Gillison
  – Dr. Loren Mell
  – Dr. Mitchell Machtay

• Role: General study oversight

• Responsibilities: Lead the design, conduct, analysis and reporting of the study
CRO (MedNet Solutions)

- **Role:** Manage study conduct, analysis and reporting
- **Responsibilities:**
  - Create budget
  - Write protocol
  - Create eCRFs and manage technology (EDC)
  - Manage Steering Committee
  - Promote the study, in collaboration with Sponsor
  - Provide clinical data review through Steering Committee
  - Issue site queries
  - Analyze data
  - Create data sharing agreement
  - Draft abstracts and manuscripts, if desired

Note: Selected tasks of the CRO may be done through subcontractors.