

Case #:

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Form I 1

History and Physical Studies

1. Weight loss within six months prior to treatment _____
 1 = No
 2 = Yes, weight loss, >= 5%
 3 = Yes, documented weight loss, % unknown
 9 = Unknown

2. If yes, how many pounds lost? (lbs) _____ (999 = unknown)

3. Pre-radiation weight (lbs) _____ (999 = unknown)

4. Post-radiation weight at the end of radiation therapy (RT) (lbs.) _____ (999 = unknown)

5. Karnofsky performance status (KPS) _____
 60 = Requires occasional assistance; cares for most needs
 70 = Cares for self; unable to carry on normal activity/work
 80 = Normal activity with effort
 90 = Minor signs or symptoms of disease
 100 = Normal
 888 = Cannot be determined
 999 = Unknown

6. Source of KPS data _____
 1 = Recorded in chart
 2 = Derived by abstractor
 8 = Could not be determined

7. Smoking status _____
 1 = Never smoked
 2 = Current smoker
 3 = Former smoker, (quit <= 1 year)
 4 = Former smoker, (quit >1 year & <= 10 years)
 5 = Former smoker, (quit >10 years)
 6 = Former smoker, (quitting period unknown)
 9 = Unknown smoking status

- Brinkmann index = # Pack-years (# packs per day x # years)*
8. # Packs per day _____ (9. = Unknown)

9. # Years _____ (99. = Unknown)

10. # Pack-years _____ (999. = unknown)

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11. FEV₍₁₎ (Forced expiratory volume in first second) _____ (Liters) (9. = *unknown*)
12. % Predicted _____ (%) (999. = *unknown*)
13. (D_{L,CO}) Carbon monoxide diffusing capacity of the lung? _____ (99. = *unknown*)
14. % Predicted _____ (%) (999. = *unknown*)

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Workup and Studies

Were the following diagnostic studies performed?

21. Chest Computed Tomography (CT) scan _____

- 1 = No
- 2 = Yes
- 9 = Unknown

22. Upper abdominal CT scan _____

- 1 = No
- 2 = Yes, separate abdominal CT
- 3 = Yes, included with chest CT
- 9 = Unknown

23. Was contrast used in abdominal CT _____

- 1 = No
- 2 = Yes
- 9 = Unknown

24. Bone scan _____

- 1 = No
- 2 = Yes
- 9 = Unknown

25. Brain CT _____

- 1 = No
- 2 = Yes
- 9 = Unknown

26. Brain Magnetic Resonance Imaging (MRI) _____

- 1 = No
- 2 = Yes
- 9 = Unknown

27. Positron emission tomography (PET) scan _____

- 1 = No
- 2 = Yes, PET only
- 3 = Yes, PET/CT
- 9 = Unknown

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Location of primary tumor:

28. Right Lung _____

- 1 = No
- 2 = Yes, upper and/or middle lobe(s)
- 3 = Yes, lower lobe
- 4 = Yes, upper and/or middle lobe(s) & lower lobe
- 9 = Unknown

29. Left Lung _____

- 1 = No
- 2 = Yes, upper and/or middle lobe(s)
- 3 = Yes, lower lobe
- 4 = Yes, upper and/or middle lobe(s) & lower lobe
- 9 = Unknown

30. Superior sulcus (Pancoast) tumor _____

- 1 = No
- 2 = Yes
- 9 = Unknown

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Clinical Staging

Clinical staging - American Joint Committee on Cancer (6th Edition) Version 02.03.02 (AJCC 02):

41. T-primary tumor _____
- 1 = TX
 - 2 = T0
 - 3 = Tis
 - 4 = T1
 - 5 = T2
 - 6 = T3
 - 7 = T4
 - 9 = Unknown
42. N-Regional lymph nodes _____
- 1 = NX
 - 2 = N0
 - 3 = N1
 - 4 = N2
 - 5 = N3
 - 9 = Unknown

Answer the following questions even if either T or N above is unknown.

Stage Grouping

43. Maximum dimension of primary tumor _____ millimeters (mm)
(999 = unknown)
44. Pulmonary nodules _____
- 1 = No
 - 10 = Yes
 - 99 = Unknown
45. Clinical stage _____
- 1 = I
 - 2 = II
 - 3 = III
 - 9 = Unknown
46. Stage group _____
- 1 = A
 - 2 = B
 - 9 = Unknown

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47. Sentinel lymph node (LN) mapping done of mediastinum _____

- 1 = No
- 2 = Yes
- 9 = Unknown

48. Mediastinum pathologically staged _____

- 1 = No
- 2 = Yes
- 9 = Unknown

If yes to Q48:

49. Transbronchial needle biopsy (WANG) _____

- 1 = No
- 2 = Yes
- 9 = Unknown

50. Transesophageal ultrasound guided biopsy _____

- 1 = No
- 2 = Yes
- 9 = Unknown

51. Mediastinoscopy _____

- 1 = No
- 2 = Yes
- 9 = Unknown

52. Mediastinotomy _____

- 1 = No
- 2 = Yes
- 9 = Unknown

53. VATS (video-assisted thoracoscopic surgery) _____

- 1 = No
- 2 = Yes
- 9 = Unknown

55. Stage changed from chart _____

- 1 = No
- 2 = Yes, incorrectly staged, or not staged, by M.D.
- 3 = Other
- 9 = Unknown

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Pathology

60. Histopathologic type _____

- 1 = Small cell lung cancer / oat cell (SCLC)
- 2 = Squamous cell
- 3 = Adenocarcinoma
- 4 = Large cell
- 5 = Non-small cell carcinoma (NSCLC), Not otherwise specified (NOS)
- 6 = NSCLC - neuroendocrine
- 7 = Alveolar or bronchoalveolar
- 8 = Adenosquamous cell
- 9 = Adenocarcinoma with bronchioloalveolar carcinoma (BAC) features
- 10 = Mixed histology (NSCLC)
- 11 = Mixed histology (SCLC)
- 12 = Mixed histology (SCLC and NSCLC)
- 99 = Unknown (e.g., not in chart)

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Treatment

71. Investigational protocol _____

- 1 = No
- 2 = Yes, National Cancer Institute (NCI) Clinical Trials Cooperative Group (*specify below*)
- 3 = Yes, Institutional Review Board (IRB)-approved institutional clinical trial
- 4 = Yes, IRB-approved Pharmaceutical Research and Manufacturers of America (PHARMA) clinical trial
- 5 = Yes, IRB-approved device clinical trial
- 8 = Other
- 9 = Unknown

If Q# 71 is Yes, option (2),

72. Protocol group & number are (*e.g., Radiation Therapy Oncology Group [RTOG 9801]*)
_____ (*9999 = Unknown*)

Treatment given

73. External Beam (not including stereotactic radiation) _____

- 1 = No
- 2 = Yes
- 9 = Unknown

74. Total dose (cGy) _____ (*9999 = Unknown*)

75. Dose/fraction (cGy) _____ (*9999 = Unknown*)

76. Split course _____

- 1 = No
- 2 = Yes
- 9 = Unknown

77. Hyper-fractionation _____

- 1 = No
- 2 = Yes
- 9 = Unknown

If yes to hyper-fractionation:

78. Specify fractional dose (cGy) _____ (*999 = Unknown*)

79. Interval between each fraction (hours) _____ (*99 = Unknown*)

80. # of fractions per day _____ (*99 = Unknown*)

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81. Brachytherapy _____

- 1 = No
- 2 = Yes
- 9 = Unknown

If yes:

82. Total Dose (cGy) _____ (9999 = Unknown)

83. # of Fractions _____ (99 = Unknown)

84. Prescription depth (cm) _____ (9. = Unknown)

85. Type _____

- 1 = Low-dose rate (LDR)
- 2 = High-dose rate (HDR)
- 3 = Other
- 9 = Unknown

86. Stereotactic Radiation _____

- 1 = No
- 2 = Yes
- 9 = Unknown

If yes:

87. Total dose _____ centi-Gray (cGy) (99999 = Unknown)

88. Dose/fraction _____ (cGy) (9999 = Unknown)

89. How many fractions per week? _____ (99 = Unknown)

90. Total # of fractions _____ (99 = Unknown)

91. Technology used for SBRT (Stereotactic Body Radiotherapy) _____

- 1 = Novalis
- 2 = TomoTherapy
- 3 = Cyberknife
- 4 = Varian Trilogy
- 5 = Novalis Tx
- 6 = Electra Synergy
- 7 = Protons
- 8 = Other
- 9 = Unknown

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92. Use of IGRT (image guided RT) for treatment delivery _____

- 1 = No
- 2 = Yes
- 9 = Unknown

If yes:

93. Which IGRT technique used _____

- 1 = Cone beam CT (CBCT)
- 2 = CT-on-rails
- 3 = Fiducials
- 4 = Exactrac
- 5 = Optical System
- 6 = Ultrasound
- 7 = Tomotherapy
- 8 = Other
- 9 = Unknown

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RT Treatment Planning

101. Was a Planning Target Volume (PTV) defined? _____

- 1 = No
- 2 = Yes
- 9 = Unknown

102. Was an ITV (internal target volume) defined? _____

- 1 = No
- 2 = Yes
- 9 = Unknown

Were the following used in treatment planning?

103. CT simulation _____

- 1 = No
- 2 = Yes
- 9 = Unknown

104. PET for treatment planning _____

- 1 = No
- 2 = Yes
- 9 = Unknown

105. 3-dimensional conformal radiation therapy (3D CRT) _____

- 1 = No
- 2 = Yes
- 9 = Unknown

106. Intensity-Modulated Radiation Therapy (IMRT) _____

- 1 = No
- 2 = Yes
- 9 = Unknown

107. 4 dimensional (4D) treatment planning (e.g., CT simulations (sims) incorporating timing)

- _____
- 1 = No
 - 2 = Yes
 - 9 = Unknown

108. Strategy to account for respiration (e.g., gating/abdominal compression /breath-hold) _____

- 1 = No
- 2 = Yes
- 9 = Unknown

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109. Patient immobilized _____

- 1 = No
- 2 = Yes
- 9 = Unknown

111. Dose volume histograms (DVH) _____

- 1 = No
- 2 = Yes
- 9 = Unknown

112. Criteria for lung toxicity (e.g., V20) _____

- 1 = No
- 2 = Yes
- 9 = Unknown

If yes:

113. What is the V20 _____ (%)

114. What is the V10? _____ (%)

115. What is the V5? _____ (%)

(888 = Cannot be computed) (889 = DVH in a different format) (999 = Unknown)

116. Mean Lung dose? _____ (cGy) (99999 = Unknown)

117. Lung heterogeneity correction _____

- 1 = No
- 2 = Yes
- 9 = Unknown

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External Beam RT Summary

121. Any external beam RT (including stereotactic radiation)? _____

- 1 = No
- 2 = Yes
- 9 = Unknown

122. Prescription _____

- 1 = Isodose
- 2 = Point (e.g., mid-plane)
- 9 = Unknown

123. Beam type _____

- 1 = Cobalt
- 2 = Photon
- 3 = Mixed
- 4 = Proton
- 5 = Electron
- 9 = Unknown

*If photons or mixed beam, specify energies (List 1 per line):
(If not done, use 88 = not applicable)*

124. Energy 1 _____ (99 = Unknown)

125. Energy 2 _____ (99 = Unknown)

126. Energy 3 _____ (99 = Unknown)

Fields included in initial RT:

127. Primary tumor mass _____

- 1 = No
- 2 = Yes
- 9 = Unknown

128. Ipsilateral hilum _____

- 1 = No
- 2 = Yes
- 9 = Unknown

129. Ipsilateral Mediastinum _____

- 1 = No
- 2 = Yes
- 9 = Unknown

130. Ipsilateral supraclavicular fossa _____

- 1 = No
- 2 = Yes
- 9 = Unknown

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131. Contralateral hilum _____

- 1 = No
- 2 = Yes
- 9 = Unknown

132. Contralateral mediastinum _____

- 1 = No
- 2 = Yes
- 9 = Unknown

133. Contralateral supraclavicular fossa _____

- 1 = No
- 2 = Yes
- 9 = Unknown

134. Fields reduced during RT _____

- 1 = No
- 2 = Yes
- 9 = Unknown

135. Maximum dose to spinal cord _____ cGy (9999 = unknown)

136. Prophylactic cranial irradiation (PCI) employed _____

- 1 = No
- 2 = Yes
- 9 = Unknown

If yes:

137. Total dose PCI (cGy) _____ (9999 = Unknown)

138. Dose/fraction (cGy) _____ (999 = Unknown)

Treatment Course:

139. Patient completed planned radiation treatment _____

- 1 = No
- 2 = Yes
- 9 = Unknown

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If no, reason:

140. Principal reason incomplete _____

- 1 = Progressive disease
- 2 = Complications
- 3 = Non-compliance/Patient refusal
- 4 = Intercurrent disease
- 5 = Other
- 9 = Unknown

141. Unplanned breaks in radiation >5 days _____

- 1 = No
- 2 = Yes
- 9 = Unknown

If yes, reason(s):

142. # 1. _____

143. # 2. _____

- 0 = None
- 1 = Equipment problem
- 2 = Non-compliance/Patient refusal
- 3 = Intercurrent disease
- 4 = Hematologic complications
- 5 = Esophageal complications
- 6 = Pulmonary complications
- 7 = Other complications
- 9 = Unknown

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Surgery

151. Surgery performed _____

- 1 = No
- 2 = Yes, lung biopsy only
- 3 = Yes, pulmonary resection
- 4 = Yes, both lung biopsy and pulmonary resection
- 5 = Yes, lung biopsy only, surgical staging Not available (N/A)
- 6 = No, mediastinum only
- 9 = Unknown

If question 151 is option 3 or 4, yes resection:

Approach to pulmonary resection:

152. Thoracotomy _____

- 1 = No
- 2 = Yes
- 9 = Unknown

153. VATS (Video-Assisted Thorascoscopic Surgery) _____

- 1 = No
- 2 = Yes
- 9 = Unknown

Extent of pulmonary resection:

154. Exploration, no resection _____

- 1 = No
- 2 = Yes
- 9 = Unknown

155. Segmentectomy _____

- 1 = No
- 2 = Yes
- 9 = Unknown

156. Lobectomy _____

- 1 = No
- 2 = Yes
- 9 = Unknown

157. Bi-lobectomy _____

- 1 = No
- 2 = Yes
- 9 = Unknown

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158. Pneumonectomy _____

1 = No

2 = Yes

9 = Unknown

159. Wedge _____

1 = No

2 = Yes

9 = Unknown

160. Residual Tumor (R) _____

1 = RX (Presence of residual tumor cannot be assessed)

2 = R0 (all margins pathologically negative)

3 = R1 (microscopically positive margins or microscopic residual disease)

4 = R2 (gross residual disease or macroscopically positive margins)

9 = Unknown

Lymph nodes resected: *(If no nodes resected, use 88 = not applicable)*

161. Total #Lymph Nodes positive _____ (99 = Unknown)

162. Total #Lymph Nodes sampled _____ (99 = Unknown)

163. Extracapsular nodal extension _____

1 = No

2 = Yes

9 = Unknown

164. Surgical T-classification (AJCC 02) _____

1 = TX

2 = T0

3 = Tis

4 = T1

5 = T2

6 = T3

7 = T4

9 = Unknown

165. Surgical N-classification _____

1 = NX

2 = N0

3 = N1

4 = N2

5 = N3

9 = Unknown

166. Stage _____

1 = I

2 = II

3 = III

9 = Unknown

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167. Group _____

1 = A

2 = B

9 = Unknown

168. Surgical Stage changed from chart? _____

1 = No

2 = Yes, incorrectly staged or not staged by MD

3 = Other

9 = Unknown

169. If other, specify _____

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Systemic Therapy (Initial Rx only)

180. Systemic therapy _____
1 = No 2 = Yes 3 = Yes, but no details available 9 = Unknown

Sequence1	Sequence2 1=No surg. 2=Pre-surg. 3=Post-surg.	Therapy Given 1 = No 2 = Yes 3 = Yes, but no information (info) 9 = Unknown	Agent 1	Agent 2	Agent 3	Agent 4
Concurrent with RT	181. _____	182. _____	183. _____ <i>If other, specify below</i> 184. _____	185. _____ <i>If other, specify below</i> 186. _____	187. _____ <i>If other, specify below</i> 188. _____	189. _____ <i>If other, specify below</i> 190. _____
Pre-RT	191. _____	192. _____	193. _____ <i>If other, specify below</i> 194. _____	195. _____ <i>If other, specify below</i> 196. _____	197. _____ <i>If other, specify below</i> 198. _____	199. _____ <i>If other, specify below</i> 200. _____
Post-RT	201. _____	202. _____	203. _____ <i>If other, specify below</i> 204. _____	205. _____ <i>If other, specify below</i> 206. _____	207. _____ <i>If other, specify below</i> 208. _____	209. _____ <i>If other, specify below</i> 210. _____
Sequence Unknown	211. _____	212. _____	213. _____ <i>If other, specify below</i> 214. _____	215. _____ <i>If other, specify below</i> 216. _____	217. _____ <i>If other, specify below</i> 218. _____	219. _____ <i>If other, specify below</i> 220. _____

Agents:

- | | |
|---|--|
| 1 = Cisplatin (<i>Platinol</i>) = CDDP | 11 = Topotecan (<i>Hycamptin</i>) |
| 2 = Etoposide (<i>VPI6</i>) | 12 = Amifostine (<i>WR2721</i>) = Ethyol |
| 3 = Premetrexed (<i>Alimta</i>) | 13 = Tirapazamine |
| 4 = Paclitaxel (<i>Taxol</i>) | 14 = Erlotinib (<i>Tarceva</i>) |
| 5 = Carboplatin (<i>Paraplatin</i>) = CBDCA | 15 = Gefitinib (<i>Iressa</i>) |
| 6 = Vinblastin9e (<i>Velban</i>) | 16 = C225 (<i>Cetuximab</i>) |
| 7 = Vinorelbine (<i>Navelbine</i>) | 17 = Bevacizumab (<i>Avastin</i>) |
| 8 = Gemcitabine (<i>Gemzar</i>) | 88 = Other |
| 9 = Docetaxel (<i>Taxotere</i>) | 99 = Unknown |
| 10 = Irinotecan (<i>CPT-11</i>) | 0 = None |

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222. If patient had surgery (with node positive disease) and did not receive chemotherapy after surgery, why not: _____

1 = Patient refusal

2 = Documentation that patient would be unable to tolerate chemotherapy

3 = No indication that patient was offered chemotherapy (or sent to medical oncologist)

4 = Chemotherapy recommended but no indication that it was done

5 = Chemotherapy before surgery

6 = Other

8 = Not applicable

9 = Unknown

223. If other, specify _____

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CHEMOTHERAPY COMMENTS

Use multiple lines, as needed. Leave blank if no Comments.

Note: DO NOT include any Personal Health Information (PHI) in these comments.

231. _____

232. _____

233. _____

234. _____

235. _____

236. _____

237. _____

238. _____

239. _____

240. _____

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Adult Comorbidity Evaluation

280. Comorbidities ____ 1 = No comorbidities 2 = Yes, one or more 9 Cannot be determined

If yes (code 2), complete table, otherwise skip to Q 306)

Comorbidity	Grade: 0 = None 1 = Grade 1 (mild) 2 = Grade 2 (mod) 3 = Grade 3 (severe) 4 = Present, grade unknown 9 = Unknown
Cardiovascular system comorbidity score (Including myocardial infarction [MI], angina /coronary artery disease [CAD], congestive heart failure [CHF], arrhythmias, hypertension [HTN], venous and peripheral arterial disease)	281. _____
Respiratory system comorbidity score (Including pulmonary insufficiency, and restrictive lung disease or chronic obstructive pulmonary disease [COPD])	283. _____
Gastrointestinal system comorbidity score (Including hepatic disease, stomach/intestine, and pancreatic disease)	285. _____
Renal system comorbidity score (End stage renal disease)	287. _____
Endocrine system comorbidity score (Including Insulin dependent diabetes mellitus, and adult onset diabetes mellitus)	289. _____
Neurological system comorbidity score (Including stroke, dementia, paralysis, and neuromuscular disorders)	291. _____
Psychiatric comorbidity score (Including major depression, bipolar disorder, and schizophrenia)	293. _____
Rheumatologic comorbidity score (Including rheumatoid arthritis, systemic lupus, connective tissue disorder, and polymyositis)	295. _____
Immunological system comorbidity score (human immunodeficiency virus [HIV], and acquired immunodeficiency syndrome [AIDS])	297. _____
Malignancy comorbidity score (Solid tumors including melanoma, leukemia, myeloma, and lymphoma)	299. _____
Substance Abuse comorbidity score (Including alcohol abuse, illicit drug abuse)	301. _____
Body weight comorbidity score (Obesity, body mass index [BMI] >= 38)	303. _____

305. Was treatment contra-indicated or changed due to comorbidities? No Yes Unknown

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GENERAL COMMENTS

Use multiple lines, as needed.

Note: DO NOT include any Personal Health Information (PHI) in these comments.

306. _____

307. _____

308. _____

309. _____

310. _____

311. _____

312. _____

313. _____

314. _____

315. _____

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Sequence of Events (SOE)

All dates will be blanked out before data are transmitted to the database. Only Elapsed days and Duration will be retained.

Events	mm/dd/yyyy	Elapsed days*	Duration (days)
<u>Pathology:</u>			
Initial biopsy/diagnosis:	321. ___/___/_____	322. _____	
<u>External Beam RT:</u>			
Start of External Beam/Chest therapy:	323. ___/___/_____	324. _____	
End of External Beam/Chest therapy:	325. ___/___/_____	326. _____	327. _____ (326-324)
Start of PCI:	328. ___/___/_____	329. _____	
<u>Surgery:</u>			
	335. ___/___/_____	336. _____	
<u>Recurrence:</u>			
First recurrence:	337. ___/___/_____	338. _____	
<u>Outcome:</u>			
Last visit:	339. ___/___/_____	340. _____	
Last contact:	341. ___/___/_____	342. _____	
Death:	343. ___/___/_____	344. _____	

* Elapsed time (in days) for an event is the date of that event minus the reference date.

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SOE COMMENTS:

Use multiple lines, as needed.

Note: DO NOT include any Personal Health Information (PHI) in these comments.

346. _____

347. _____

348. _____

349. _____

350. _____

351. _____

352. _____

353. _____

354. _____

355. _____