

Case #:

Institution #:

Form I 1

History

1. Karnofsky performance status _____
60 = Requires occasional assistance
70 = Unable to carry on normal activity/work
80 = Normal activity with effort
90 = Minor signs or symptoms of disease
100 = Normal
999 = Unknown

2. Weight loss pre-Radiation Therapy (RT) _____
1 = No
2 = Yes
9 = Unknown

3. Weight at start of radiation treatment (lbs.) _____ (999 = Unknown)

4. Parenteral nutritional support pre-RT _____
1 = No
2 = Yes
9 = Unknown

5. Enteral nutritional support (e.g., feeding tube) pre-RT _____
1 = No
2 = Yes
9 = Unknown

6. Gastrointestinal (GI) Bleeding _____
1 = No
2 = Yes
3 = Yes, transfusion required
9 = Unknown

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Workup and Studies

11. Barium swallow performed _____ 1 = No 2 = Yes 9 = Unknown
 12. Endoscopy performed _____ 1 = No 2 = Yes 9 = Unknown
 13. Endoscopic Ultrasound _____ 1 = No 2 = Yes 9 = Unknown

If Q13 is yes, complete Qs 14-16

14. Endoscopic ultrasound (EUS) cranial-caudal extent from the incisors for gastroesophageal (GE) junction tumor: _____ millimeters (mm) (888=not applicable; 999=unknown)

15. Endoscopic US-T-classification AJCC 02 American Joint Committee on Cancer 6th Edition, 02.03.02 _____

- 1 = TX
- 2 = T0
- 3 = Tis
- 4 = T1
- 5 = T2
- 6 = T2a
- 7 = T2b
- 8 = T3
- 9 = T4
- 99 = Unknown

16. Endoscopic US- N-classification (AJCC 02) _____

- 1 = NX
- 2 = N0
- 3 = N1
- 4 = N2
- 5 = N3
- 9 = Unknown

17. Chest Computed Tomography (CT) performed _____ 1 = No 2 = Yes 9 = Unknown

18. Abdominal CT performed _____ 1 = No 2 = Yes 9 = Unknown

If yes to Q 17 or 18, complete Qs 19 & 20

19. Chest/Abdominal CT-T-classification (AJCC 02) _____

- 1 = TX
- 2 = T0
- 3 = Tis
- 4 = T1
- 5 = T2
- 6 = T2a
- 7 = T2b
- 8 = T3
- 9 = T4
- 99 = Unknown

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20. Chest/Abdominal CT – N-classification (AJCC 02) _____

- 1 = NX
- 2 = N0
- 3 = N1
- 4 = N2
- 5 = N3
- 9 = Unknown

Additional diagnostic methods used to detect regional nodes (Peri-esophageal and Mediastinal)

21. Laparoscopy _____

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

22. Positron emission tomography (PET) _____

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

23. Magnetic Resonance Imaging (MRI) _____

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

24. Other _____

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

If other, specify:

25. _____

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Staging & Extent of Disease

31. Histology _____
1 = Squamous cell
2 = Adenocarcinoma
3 = Adenosquamous
9 = Unknown
32. Grade _____
1 = GX = Grade cannot be assessed
2 = G1 = Well differentiated
3 = G2 = Moderately-differentiated
4 = G3 = Poorly-differentiated
9 = Unknown
33. Signet cell features _____
1 = No
2 = Yes
9 = Unknown
34. Clinical Stage: (AJCC 02) _____
1 = 0
2 = 1A
3 = 1B
4 = II
5 = IIIA
6 = IIIB
7 = IV
9 = Unknown
35. Surgical T-classification (AJCC 02) _____
0 = Not applicable/Surgery not performed
1 = TX
2 = T0
3 = T1
4 = T2
5 = T2a
6 = T2b
7 = T3
8 = T4
9 = Unknown
36. Surgical N-classification (AJCC 02) _____
0 = Not applicable
1 = NX
2 = N0
3 = N1
4 = N2
5 = N3
9 = Unknown

Quality Research in Radiation Oncology
3707 Gastric Process

American College of Radiology 1818 Market Street -16th Floor Philadelphia, PA 19103 215-574-3164

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37. Primary location of tumor per pathology report _____

- 1 = Antrum
- 2 = Corpus
- 3 = Cardia
- 4 = GE junction
- 9 = Unknown

38. Maximum dimension of primary tumor per pathology report _____ mm (999 = *unknown*)

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Treatment Course

51. Investigational protocol _____

1 = No

2 = Yes, National Cancer Institute (NCI) Clinical Trials Cooperative Group or other external clinical trials (*Specify below.*)

3 = Yes, Institutional Review Board (IRB)-approved institutional clinical trials

4 = Yes, IRB-approved Pharmaceutical Research and Manufacturers of America (PHARMA) or Device, Clinical Trial

5 = Other

9 = Unknown

If Yes (2),

52. Protocol group & number (e.g., Radiation Therapy Oncology Group [RTOG] 9709) _____ (*9999 = Unknown*)

Planned Treatment:

53. External beam _____

1 = No

2 = Yes

9 = Unknown

54. Surgical resection _____

1 = No

2 = Yes

9 = Unknown

55. Chemotherapy _____

1 = No

2 = Yes

9 = Unknown

Treatment Given:

56. External beam _____

1 = No

2 = Yes

9 = Unknown

57. Surgical resection _____

1 = No

2 = Yes

9 = Unknown

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59. When was radiation delivered _____
0 = No surgical resection
1 = post-surgery
2 = pre-surgery
3 = both
9 = Unknown

60. Planned radiation treatment completed _____
1 = No
2 = Yes
9 = Unknown

If No (not completed),

61. Primary reason RT incomplete _____
1 = Progressive disease
2 = Complications
3 = Non-compliance/Patient refusal
4 = Intercurrent disease
5 = Death
6 = Other
9 = Unknown

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Surgery

71. Type of surgical resection per operative report _____
 0 = No surgical resection
 1 = Total gastrectomy
 2 = Partial gastrectomy
 3 = Esophago-gastrectomy
 4 = Other
 5 = Nodal resection only
 9 = Unknown

72. Was resection performed laparoscopically? _____
 1 = No
 2 = Yes
 9 = Unknown

73. Contiguous organ removal per pathology & operative reports _____
 1 = No
 2 = Yes
 9 = Unknown

If yes,

Contiguous Organs	Organ removed 1 = Not removed 2 = Yes 9 = unknown
Spleen	74. _____
Pancreas	75. _____
Liver	76. _____
Other	77. _____
Site unknown	78. _____

79. Completion of primary resection per pathology & operative reports _____
 1 = RX (Presence of residual tumor cannot be assessed)
 2 = RO (complete resection with negative margins)
 3 = R1 (microscopically positive margins or microscopic residual disease)
 4 = R2 (gross residual disease or macroscopically positive margins)
 9 = Unknown

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80. Completion of lymph node resection per pathology & operative reports of Gastric tumors _____

- 1 = Not done
- 2 = Yes
- 9 = Unknown

If yes, complete table; otherwise, skip to Q 101:

Site of lymph node resection	Nodes resected 1 = Not resected 2 = Yes 9 = Unknown
Perigastric nodes	81. _____
Celiac	82. _____
Splenic artery	83. _____
Splenic hilar	84. _____
Other	85. _____
Site unknown	86. _____
Porta hepatis	96. _____
Periesophageal	97. _____
Splenic, Not otherwise specified (NOS)	98. _____

87. Total number of lymph nodes resected per pathology report _____
(0 = none, 99 = unknown)

88. Total number of positive lymph nodes per pathology report _____
(0 = none, 99 = unknown)

Lymph Node (LN) - Comments

Use multiple lines, as needed.

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

91. _____

92. _____

93. _____

94. _____

95. _____

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External Beam

101. Prescription _____

- 1 = Isodose
- 2 = Point
- 9 = Unknown

102. Photon Energy _____ *megavolts (MV)*

- 1 = <=6
- 2 = 7-9
- 3 = 10-15
- 4 = >15
- 5 = Co60
- 6 = Mixed Energies
- 9 = Unknown

103. Total dose given *centi-Gray (cGy)* _____

104. Dose/fx (cGy) _____

106. Total # of Fractions _____

107. All fields treated each day _____

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

108. Fields reduced during RT _____

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

109. Treatment position _____

- 1 = Prone
- 2 = Supine
- 3 = Both prone and supine
- 9 = Unknown

113. Technique _____

- 1 = AP/PA
- 2 = 3 field
- 3 = 4 field
- 4 = >4 field
- 8 = Other
- 9 = Unknown

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114. CT based treatment plan _____

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

If 1 or 9, skip to Q 123.

If yes (code 2),

115. 3-dimensional conformal radiation therapy (3D-CRT) _____

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

116. If 3-D planning performed, were dose volume histograms of both kidneys performed _____

- 1 = No
- 2 = Yes
- 8 = Not applicable
- 9 = Unknown

If Q 116 is yes,

117. Was at least 67% of one kidney kept at or below 20 Gy _____

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

118. If 3-D planning performed, were dose volume histograms of the liver performed _____

- 1 = No
- 2 = Yes
- 8 = Not applicable
- 9 = Unknown

If yes,

119. Was at least 40% of the liver kept at or below 30 Gy _____

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

120. In GE junction tumors, if 3-D planning performed, were dose volume histograms of the heart performed _____

- 1 = No
- 2 = Yes
- 8 = Not applicable
- 9 = Unknown

121. *If yes,* was at least 40% of the heart kept at or below 30 Gy _____

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

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122. If 3-D planning performed, did the planning tumor volume receive at least 95% of the prescribed dose _____
 1 = No
 2 = Yes
 8 = Not applicable
 9 = Unknown

123. Was Intensity-Modulated Radiation Therapy (IMRT) used _____
 1 = No
 2 = Yes
 9 = Unknown

124. Parenteral nutritional support during RT _____
 1 = No
 2 = Yes
 9 = Unknown

125. Enteral nutritional support during RT (e.g., feeding tube) _____
 1 = No
 2 = Yes
 9 = Unknown

126. Weight at end of radiation treatment (lbs.) _____ (999 = Unknown)

Image guided tools, other than CT, used in the radiation planning and treatment delivery:

127. PET _____

128. MRI _____

129. Respiratory gating
 and/or 4D-CT _____

130. On-board imaging _____



0 = Not used
 1 = Used in both radiation planning & delivery
 2 = Used in radiation planning only
 3 = Used in treatment delivery only
 9 = Unknown

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Comprehensive Care

131. Did the radiation oncologist first meet with the patient? _____
1 = pre-operatively
2 = post-operatively
8 = not applicable
9 = Unknown
132. Was the case discussed in a multi-disciplinary tumor board? _____
1 = No
2 = Yes
9 = Unknown
136. Was acute toxicity (*during radiation treatment*) assessed? _____
1 = No
2 = Yes, using a standard numerical scoring system (e.g. RTOG or NCI CTC)
3 = Yes, descriptive assessment only
9 = Unknown
137. Was late toxicity (*after radiation treatment*) assessed? _____
(*up to 24 months post-treatment*)
1 = No
2 = Yes, using a standard numerical scoring system (e.g. RTOG or NCI CTC)
3 = Yes, descriptive assessment only
9 = Unknown
138. Was the patient seen by the radiation oncologist in follow-up? _____
1 = No
2 = Yes, 1 visit only
3 = Yes, > 1 visit
9 = Unknown

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Chemotherapy

140. Chemotherapy given _____
1 = No 2 = Yes 3 = Yes, but no details 9 = Unknown

If Q 140 is yes, complete table; otherwise, skip to Comments (Q 186)

Sequence1	Sequence2 1=No surgery 2=Pre-surgery 3=Post-surgery	Therapy Given	Agent 1	Agent 2	Agent 3	Agent 4
Concurrent with RT	141. _____	142. _____ 1 = No 2 = Yes 3 = Yes, but no details 9 = Unknown	143. _____ If other, specify below 144. _____	145. _____ If other, specify below 146. _____	147. _____ If other, specify below 148. _____	149. _____ If other, specify below 150. _____
Pre-RT	151. _____	152. _____ 1 = No 2 = Yes 3 = Yes, but no details 9 = Unknown	153. _____ If other, specify below 154. _____	155. _____ If other, specify below 156. _____	157. _____ If other, specify below 158. _____	159. _____ If other, specify below 160. _____
Post-RT	161. _____	162. _____ 1 = No 2 = Yes 3 = Yes, but no details 9 = Unknown	163. _____ If other, specify below 164. _____	165. _____ If other, specify below 166. _____	167. _____ If other, specify below 168. _____	169. _____ If other, specify below 170. _____
Sequence Unknown	171. _____	172. _____ 1 = No 2 = Yes 3 = Yes, but no details 9 = Unknown	173. _____ If other, specify below 174. _____	175. _____ If other, specify below 176. _____	177. _____ If other, specify below 178. _____	179. _____ If other, specify below 180. _____

Agents:

- | | | |
|--------------------|------------------|--------------------|
| 1 = bolus 5FU | 10 = Oxaliplatin | 18 = VP16 |
| 2 = infusional 5FU | 11 = Paclitaxel | 19 = Vinblastine |
| 3 = Cisplatin | 12 = Docetaxel | 20 = Cetuximab |
| 4 = Carboplatin | 13 = Irinotecan | 21 = Bevacizumab |
| 6 = Leucovorin | 14 = Taxane | 22 = 5 FU NOS |
| 7 = Taxol | 15 = Taxotere | 88 = Other |
| 8 = Capecitabine | 16 = ECF | 99 = Unknown |
| 9 = Epirubicin | 17 = Mitomycin | 0 = Not applicable |

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COMMENTS

Use multiple lines, as needed.

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

186. _____

187. _____

188. _____

189. _____

190. _____

191. _____

192. _____

193. _____

194. _____

195. _____

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Adult Comorbidity Evaluation

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

Comorbidity	Grade: 0 = None 1 = Grade 1 (<i>mild</i>) 2 = Grade 2 (<i>mod</i>) 3 = Grade 3 (<i>severe</i>) 4 = Present, grade unknown 9 = Unknown
Cardiovascular system comorbidity score (<i>Including myocardial infarction [MI], angina / coronary artery disease [CAD], congestive heart failure [CHF], arrhythmias, hypertension [HTN], venous and peripheral arterial disease</i>)	201. _____
Respiratory system comorbidity score (<i>Including pulmonary insufficiency, and restrictive lung disease or chronic obstructive pulmonary disease [COPD]</i>)	203. _____
Gastrointestinal system comorbidity score (<i>Including hepatic disease, stomach/intestine, and pancreatic disease</i>)	205. _____
Renal system comorbidity score (<i>End stage renal disease</i>)	207. _____
Endocrine system comorbidity score (<i>Including Insulin dependent diabetes mellitus, and adult onset diabetes mellitus</i>)	209. _____
Neurological system comorbidity score (<i>Including stroke, dementia, paralysis, and neuromuscular disorders</i>)	211. _____
Psychiatric comorbidity score (<i>Including major depression, bipolar disorder, and schizophrenia</i>)	213. _____
Rheumatologic comorbidity score (<i>Including rheumatoid arthritis, systemic lupus, connective tissue disorder, and polymyositis</i>)	215. _____
Immunological system comorbidity score (<i>human immunodeficiency virus [HIV], and acquired immunodeficiency syndrome [AIDS]</i>)	217. _____
Malignancy comorbidity score (<i>Solid tumors including melanoma, leukemia, myeloma, and lymphoma</i>)	219. _____
Substance Abuse comorbidity score (<i>Including alcohol abuse, illicit drug abuse</i>)	221. _____
Body weight comorbidity score (<i>Obesity, body mass index [BMI] >= 38</i>)	223. _____

225. 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.

230. _____

231. _____

232. _____

233. _____

234. _____

235. _____

236. _____

237. _____

238. _____

239. _____

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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	<i>mm/dd/yyyy</i>	Elapsed days*	Duration (days)
<u>Surgical Pathology & Staging:</u>			
Initial biopsy/diagnosis:	241. ___/___/___	242. _____	
Resection:	243. ___/___/___	244. _____	
<u>External Beam RT:</u>			
Start of External Beam/Chest therapy:	245. ___/___/___	246. _____	
End of External Beam/Chest therapy:	247. ___/___/___	248. _____	249. _____ (248-246)

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

SOE COMMENTS:

Use multiple lines, as needed.

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

260. _____

261. _____

262. _____

263. _____

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SOE COMMENTS (continued):

264. _____

265. _____

266. _____

267. _____

268. _____

269. _____