



Breast Cancer Pre-HSCT Data

Registry Use Only

Sequence
Number:

Date
Received:

CIBMTR Center Number:

CIBMTR Recipient ID:

Today's Date:

Month Day Year

Date of HSCT for which this form is
being completed:

Month Day Year

HSCT type: autologous allogeneic, unrelated allogeneic, related syngeneic (identical twin)

Product type: marrow PBSC cord blood other product, specify: _____

This form must be accompanied by Form 2000 – Recipient Baseline Data. All information in the box above, including the date, should be identical with the corresponding Form 2000. Information should come from an actual examination by the Transplant Center physician, or the physician who is following the recipient pre-HSCT, or abstraction of the recipient’s medical records.

If this HSCT was performed after the occurrence of a second primary breast cancer, copy questions 1–174 and report the staging and treatment of each primary occurrence separately.

If this is a report of a second (or subsequent) transplant, check here and continue with question 175.

Disease Assessment at Diagnosis

1. What was the date of pathologic diagnosis of breast cancer?

Month Day Year

2. What was the stage of breast cancer at diagnosis?

- 1 in situ
- 2 I — T₁ N₀ M₀
- 3 II — T₀₋₁ N₁ M₀ -or- T₂ N₀₋₁ M₀ -or- T₃ N₀ M₀
- 4 IIIA — T₀₋₂ N₂ M₀ -or- T₃ N₁₋₂ M₀
- 5 IIIB — T₄ N_{any} M₀, T_{any} N₃ M₀, inflammatory
- 6 IV — T_{any} N_{any} M₁
- 7 unknown

3. Was the breast cancer considered inflammatory at diagnosis?

- 1 yes
- 2 no

4. What was the histology of breast cancer at diagnosis?

- 1 invasive / infiltrating ductal
- 2 invasive lobular
- 4 other →

5. Specify histology: _____

6. For the histology at diagnosis (question 3), is a copy of the pathology report or other documentation attached?

- 1 yes
- 2 no

7. What was the location of the breast cancer at diagnosis?

- 1 right breast
- 2 left breast
- 3 bilateral

Mail this form to your designated campus (Milwaukee or Minneapolis). Retain the original at the transplant center.

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8. What was the menopausal status of the recipient at diagnosis?

- 1 pre-menopausal
- 2 post-menopausal
- 3 not applicable, male recipient
- 4 unknown

9. Specify the recipient's age at menopause: years

10. Were metastases (other than ipsilateral axillary lymph nodes) present at diagnosis?

- 1 yes
- 2 no
- 3 unknown

Specify site(s) of metastasis:

- 11. 1 yes 2 no bone
- 12. 1 yes 2 no bone marrow
- 13. 1 yes 2 no brain
- 14. 1 yes 2 no chest wall
- 15. 1 yes 2 no liver
- 16. 1 yes 2 no lung
- 17. 1 yes 2 no lymph nodes (not ipsilateral axillary)

24. 1 yes 2 no skin

25. 1 yes 2 no other site

27. Was the metastatic disease confirmed by a biopsy of the metastatic site?

- 1 yes
- 2 no

Specify lymph nodes:

- 18. 1 yes 2 no contralateral internal mammary nodes
- 19. 1 yes 2 no mediastinum
- 20. 1 yes 2 no subclavicular
- 21. 1 yes 2 no supraclavicular
- 22. 1 yes 2 no other

23. Specify: _____

26. Specify site: _____

Tumor and Lymph Node Assessment at Diagnosis

The following questions 28–49 refer to the time of definitive surgery or, if surgery was not performed, to the time immediately prior to any initial non-surgical disease treatment.

28. Clinical size of the primary tumor (at the time of surgery or at the time of non-surgical treatment, if surgery was not performed):

- 1 known cm not measurable
- 2 not known

29. Radiographic size of the primary tumor (at the time of surgery or at the time of non-surgical treatment, if surgery was not performed):

- 1 known cm not measurable
- 2 not known

30. Pathologic size of the primary tumor (at the time of surgery):

- 1 known cm not measurable
- 2 not known

31. Was the primary tumor multicentric?

- 1 yes
- 2 no
- 3 unknown

32. Was sentinel lymph node mapping performed?

- 1 yes
- 2 no

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33. Were axillary nodes examined by any method?

- 1 yes →
2 no

34. Specify the number of axillary nodes examined:

35. How many axillary nodes were positive for breast cancer?

- 1 known →
2 not known

36. Were estrogen receptor assays performed?

- 1 yes →
2 no
3 unknown

37. Specify estrogen receptor assay results:

- 1 positive →
2 negative
3 borderline
4 unknown

38. Specify percentage of positive estrogen receptors: %

39. Were progesterone receptor assays performed?

- 1 yes →
2 no
3 unknown

40. Specify progesterone receptor assay results:

- 1 positive →
2 negative
3 borderline
4 unknown

41. Specify percentage of positive progesterone receptors: %

42. Was the breast cancer tissue or a blood sample assessed for the Her-2/*neu* oncogene?

- 1 yes →
2 no
3 unknown

43. Was immunohistochemistry (IHC) used to assess the Her-2/*neu* status?

- 1 yes →
2 no

44. Specify the level of HER2/*neu* protein expression:

- 1 indeterminate
2 negative (0 or 1+)
3 positive (2+ or 3+)

45. Was fluorescent in situ hybridization (FISH) used to assess the Her-2/*neu* gene?

- 1 yes →
2 no

46. Specify the ratio of HER2 signals to 17 centromere signals:

- 1 zero / negative / normal (< 1.8)
2 equivocal (1.8–2.0)
2 positive (> 2.0)

47. Was the proliferative index of the breast cancer quantified?

- 1 yes →
2 no
3 unknown

48. Specify the proliferative index value: %

49. Specify the index used to report the value:

- 1 3H-thymidine labeling index
2 cyclin-dependent kinase (Cdk) inhibitors
3 cyclin D1
4 cyclin E
5 flow cytometry
6 p21WAF1/CIP1
7 proliferation associated
8 topoisonmerase II α
9 thymidine kinase

Pre-HSCT Treatment for Breast Cancer

50. Was therapy given between diagnosis and the start of the preparative regimen?

- 1 yes →
2 no

Line of Therapy:	1st Line of Therapy			2nd Line of Therapy		
Systemic Therapy:	51. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no →	cont. with q. 89	113. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no →	cont. with q. 151
Date therapy started:	52. <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	114. <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>
Date therapy stopped:	53. <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	115. <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>
Number of cycles:	54. <input type="text"/> <input type="text"/>	<input type="checkbox"/> unknown/not applicable		116. <input type="text"/> <input type="text"/>	<input type="checkbox"/> unknown/not applicable	
Was therapy given prior to any surgery (neoadjuvant)?	55. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	117. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
5-fluorouracil (5-FU, Adrucil)	56. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	118. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
anastrozole (Arimidex)	57. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	119. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
bevacizumab (Avastin)	58. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	120. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
capecitabine (Xeloda)	59. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	121. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
cisplatin (Platinol, CDDP)	60. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	122. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
cyclophosphamide (CTX)	61. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	123. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
daunorubicin (Cerubidine)	62. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	124. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
daunorubicin liposomal	63. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	125. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
docetaxel (Taxotere)	64. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	126. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
doxorubicin (Adriamycin)	65. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	127. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
doxorubicin liposomal (Doxil)	66. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	128. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
epirubicin (Ellence)	67. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	129. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
exemestane (Aromasin)	68. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	130. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
gemcitabine (Gemzar)	69. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	131. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
goserelin acetate (Zoladex)	70. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	132. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
idarubicin (Idamycin)	71. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	133. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
lapatinib (Tykerb)	72. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	134. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
letrozole (Femara)	73. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	135. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
megestrol (Megace)	74. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	136. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
methotrexate (MTX, Folex)	75. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	137. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
mitoxantrone (Novantrone)	76. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	138. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
paclitaxel (Abraxane, Taxol)	77. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	139. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
pamidronate (Aredia)	78. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	140. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
tamoxifen (Nolvadex)	79. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	141. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
thiotepa (Thioplex)	80. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	142. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
toremifene (Fareston)	81. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	143. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
trastuzumab (Herceptin)	82. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no →	cont. with q. 84	144. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no →	cont. with q. 146
specify number of doses	83. <input type="text"/> <input type="text"/>			145. <input type="text"/> <input type="text"/>		
vinblastine (VLB, Velban)	84. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	146. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
vinorelbine (Navelbine)	85. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	147. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
zoledronic acid (Zometa)	86. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	148. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
other systemic therapy	87. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no	149. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no
specify other therapy	88. _____			150. _____		
Radiation Therapy:	89. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no →	cont. with q. 97	151. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no →	cont. with q. 159
Date therapy started:	90. <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	152. <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>
Date therapy stopped:	91. <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	153. <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>
Local / regional	92. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no →	cont. with q. 94	154. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no →	cont. with q. 156
Specify total dose:	93. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	cGy (rads)		155. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	cGy (rads)	
Other radiotherapy site	94. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no →	cont. with q. 97	156. 1 <input type="checkbox"/> yes	2 <input type="checkbox"/> no →	cont. with q. 159
Specify other radiation site:	95. _____			157. _____		
Specify total dose:	96. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	cGy (rads)		158. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	cGy (rads)	

CIBMTR Center Number:

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Surgery (not biopsy): 97. 1 yes 2 no → cont. with 103 159. 1 yes 2 no → cont. with q. 165

Date of surgery: 98.

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 160.

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Month Day Year Month Day Year

lumpectomy 99. 1 yes 2 no 161. 1 yes 2 no
 mastectomy 100. 1 yes 2 no 162. 1 yes 2 no
 other surgery 101. 1 yes 2 no 163. 1 yes 2 no
 specify other surgery 102. _____ 164. _____

Was recipient on a study? 103. 1 yes 2 no → cont. with 105 165. 1 yes 2 no → cont. with q. 167
 specify study: 104. _____ 166. _____

Was this line of therapy given for stem cell priming? 105. 1 yes 2 no 167. 1 yes 2 no

Best Response to Line of Therapy: (see definitions below)

	106. Non-Bone Response Code (see codes below)	108. Bone Response Code (see codes below)	168. Non-Bone Response Code (see codes below)	170. Bone Response Code (see codes below)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If non-bone code is "1" was the complete response pathologically confirmed? 107. 1 yes 2 no 169. 1 yes 2 no

Date response established: 109.

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 171.

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Month Day Year Month Day Year

Did disease relapse/progress following this line of therapy? 110. 1 yes 2 no 172. 1 yes 2 no

Date of relapse/progression: 111.

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 173.

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Month Day Year Month Day Year

Specify site(s) of relapse/progression: 112. _____ 174. _____

Copy this page to report more than 2 lines of therapy; check here if additional pages are attached.

Non-Bone Best Response Codes — Response Evaluation Criteria in Solid Tumors (RECIST)

- 1 complete response (CR) — disappearance of all target lesions for a period of at least one month
- 2 complete response with persistent imaging abnormalities of unknown significance (CRU)
- 3 partial response (PR) — at least 30% decrease in the sum of the longest diameter of measured lesions (target lesions) taking as reference the baseline sum of longest diameters
- 4 stable disease (SD) — neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference the smallest sum of the longest diameters since the treatment started
- 5 progressive disease (PD) — at least a 20% increase in the sum of the longest diameter of measured lesions (target lesions), taking as reference the smallest sum of the longest diameters recorded since the treatment started or the appearance of one or more new lesions
- 6 not assessed (NA)

Bone Best Response Codes

- 1 no prior bone disease
- 2 symptomatic improvement, no progression
- 3 symptomatic and radiographic (not bone scan only) improvement
- 4 no response
- 5 progressive disease
- 6 not assessed / radiographic data not available

CIBMTR Center Number:

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Most Recent Disease Assessment Prior to the Start of the Preparative Regimen

175. Was a bone marrow biopsy performed prior to the preparative regimen (high-dose therapy)?

- 1 yes
2 no

176. Date of most recent bone marrow biopsy:
Month Day Year

177. Was breast cancer present?

- 1 yes
2 no

Specify detection method and result:

Positive Negative Not tested

178. 1 2 3 Cell culture technique
179. 1 2 3 Immunohistochemistry (IHC)
180. 1 2 3 Polymerase chain reaction (PCR)
181. 1 2 3 Routine histopathology
182. 1 2 3 Other method

183. Specify:

184. Did the recipient ever have bone marrow involvement with breast cancer (other than the involvement indicated at question 175)?

- 1 yes
2 no

Specify detection method and result:

Positive Negative Not tested

185. 1 2 3 Cell culture technique
186. 1 2 3 Immunohistochemistry (IHC)
187. 1 2 3 Polymerase chain reaction (PCR)
188. 1 2 3 Routine histopathology
189. 1 2 3 Other method

190. Specify:

Specify all sites of disease involvement:

	Present at any time between diagnosis and HSCT?			Present immediately prior to the start of the preparative regimen?		
	Yes	No	Unknown	Yes	No	Unknown
Bone — radiographic	191. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	192. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>
Bone — symptomatic	193. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	194. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>
Brain	195. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	196. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>
Breast	197. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	198. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>
Chest wall	199. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	200. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>
Liver	201. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	202. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>
Lung	203. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	204. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>
Axillary lymph nodes	205. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	206. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>
Other lymph nodes	207. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	208. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>
Pleura	209. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	210. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>
Skin	211. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	212. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>
Other	213. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	214. 1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>

215. Specify other site:

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216. What was the sensitivity of the breast cancer to chemotherapy prior to the preparative regimen? (*Report response to last chemotherapy given prior to HSCT; chemotherapy must include ≥ 2 cycles treatment given ≤ 6 months prior to HSCT. Response must be consistent with the last line of therapy reported on page 4.*)

- 1 sensitive — $\geq 50\%$ reduction in bidimensional diameter of all disease sites with no new sites of disease
- 2 resistant — $< 50\%$ reduction in diameter of all disease sites or development of new disease sites
- 3 untreated / last line of therapy was surgery or radiation, not chemotherapy
- 4 unknown
- 5 chemotherapy was only given as adjuvant to the primary surgery or radiation therapy

Disease Status at the Last Assessment Prior to the Preparative Regimen

217. What was the disease status immediately prior to the preparative regimen? (*Should match status after last line of therapy.*)
(*Disease status based on Response Evaluation Criteria in Solid Tumors (RECIST) criteria.*)

- 1 complete response(CR) — disappearance of all target lesions for a period of at least one month
- 2 complete response with persistent imaging abnormalities of unknown significance (CRU)
- 3 partial response(PR) — at least 30% decrease in the sum of the longest diameter of measured lesions (target lesions) taking as reference the baseline sum of longest diameters
- 4 stable disease(SD) — neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference the smallest sum of the longest diameters since the treatment started
- 5 progressive disease (PD) — at least a 20% increase in the sum of the longest diameter of measured lesions (target lesions), taking as reference the smallest sum of the longest diameters recorded since the treatment started or the appearance of one or more new lesions
- 6 not assessed →
- 7 unknown / not tested

219. Date of the most recent assessment for disease status prior to the preparative regimen:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Month		Day		Year	

220. Signed: _____
Person completing form

Please print name: _____

Phone: (_____) _____

Fax: (_____) _____

E-mail address: _____