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

2. What was the stage of breast cancer at diagnosis?  
   - In situ
   - I — T1 N0 M0
   - II — T0-1 N1 M0
   - II — T2 N0-1 M0
   - IIIA — T0-2 N2 M0
   - IIIB — T4 Nany M0, Tany N3 M0, inflammatory
   - IV — Tany Nany M1
   - unknown

3. Was the breast cancer considered inflammatory at diagnosis?  
   - yes
   - no

4. What was the histology of breast cancer at diagnosis?  
   - invasive / infiltrating ductal
   - invasive lobular
   - other

5. Specify histology:

6. For the histology at diagnosis (question 3), is a copy of the pathology report or other documentation attached?  
   - yes
   - no

7. What was the location of the breast cancer at diagnosis?  
   - right breast
   - left breast
   - bilateral
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)
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

Specify lymph nodes:
23. Specify:

24. 1 ☐ yes 2 ☐ no skin

25. 1 ☐ yes 2 ☐ no other site

26. Specify site:

27. Was the metastatic disease confirmed by a biopsy of the metastatic site?
1 ☐ yes
2 ☐ no

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  
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  
2 ☐ not known

30. Pathologic size of the primary tumor (at the time of surgery):  
1 ☐ known  
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
33. Were axillary nodes examined by any method?
- [ ] yes
- [ ] no

34. Specify the number of axillary nodes examined: 

35. How many axillary nodes were positive for breast cancer?
- [ ] known
- [ ] not known

36. Were estrogen receptor assays performed?
- [ ] yes
- [ ] no
- [ ] unknown

37. Specify estrogen receptor assay results:
- [ ] positive
- [ ] negative
- [ ] borderline
- [ ] unknown

38. Specify percentage of positive estrogen receptors: %

39. Were progesterone receptor assays performed?
- [ ] yes
- [ ] no
- [ ] unknown

40. Specify progesterone receptor assay results:
- [ ] positive
- [ ] negative
- [ ] borderline
- [ ] 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?
- [ ] yes
- [ ] no
- [ ] unknown

43. Was immunohistochemistry (IHC) used to assess the Her-2/neu status?
- [ ] yes
- [ ] no

44. Specify the level of HER2/neu protein expression:
- [ ] indeterminate
- [ ] negative (0 or 1+)
- [ ] positive (2+ or 3+)

45. Was fluorescent in situ hybridization (FISH) used to assess the Her-2/neu gene?
- [ ] yes
- [ ] no

46. Specify the ratio of HER2 signals to 17 centromere signals:
- [ ] zero / negative / normal (< 1.8)
- [ ] equivocal (1.8–2.0)
- [ ] positive (> 2.0)

47. Was the proliferative index of the breast cancer quantified?
- [ ] yes
- [ ] no
- [ ] unknown

48. Specify the proliferative index value: %

49. Specify the index used to report the value:
- [ ] 3H-thymidine labeling index
- [ ] cyclin-dependent kinase (Cdk) inhibitors
- [ ] cyclin D1
- [ ] cyclin E
- [ ] flow cytometry
- [ ] p21WAF1/CIP1
- [ ] proliferation associated
- [ ] topoisomerase II α
- [ ] 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

<table>
<thead>
<tr>
<th>Line of Therapy</th>
<th>1st Line of Therapy</th>
<th>2nd Line of Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systemic Therapy:</td>
<td>51.</td>
<td>1 yes  2 no  cont. w/ q. 89</td>
</tr>
<tr>
<td>Date therapy started:</td>
<td>52.</td>
<td>Month  Day  Year</td>
</tr>
<tr>
<td>Date therapy stopped:</td>
<td>53.</td>
<td>Month  Day  Year</td>
</tr>
<tr>
<td>Number of cycles:</td>
<td>54.</td>
<td>1 unknown/not applicable 116.</td>
</tr>
<tr>
<td>Was therapy given prior to any surgery (neoadjuvant)?</td>
<td>55.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>5-fluorouracil (5-FU, Adrucil)</td>
<td>56.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>anastrozole (Arimidex)</td>
<td>57.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>bevacizumab (Avastin)</td>
<td>58.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>capcitabine (Xeloda)</td>
<td>59.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>cisplatin (Platinol, CDDP)</td>
<td>60.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>cyclophosphamide (CTX)</td>
<td>61.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>daunorubicin (Cerubidine)</td>
<td>62.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>daunorubicin liposomal</td>
<td>63.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>docetaxel (Taxotere)</td>
<td>64.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>doxorubicin (Adriamycin)</td>
<td>65.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>doxorubicin liposomal (Doxil)</td>
<td>66.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>epirubicin (Ellicite)</td>
<td>67.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>exemestene (Aromasin)</td>
<td>68.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>gemcitabine (Gemzar)</td>
<td>69.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>goserelin acetate (Zoladex)</td>
<td>70.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>idarubicin (Idamycin)</td>
<td>71.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>lapatinib (Tykerb)</td>
<td>72.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>letrozole (Femara)</td>
<td>73.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>megestrol (Megace)</td>
<td>74.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>methotrexate (MTX, Folex)</td>
<td>75.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>mitoxantrone (Novantrone)</td>
<td>76.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>paclitaxel (Abraxane, Taxol)</td>
<td>77.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>pamidronate (Aredia)</td>
<td>78.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>tamoxifen (Nolvadex)</td>
<td>79.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>thiopeta (Triplex)</td>
<td>80.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>toremifene (Fareston)</td>
<td>81.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>trastuzumab (Herceptin)</td>
<td>82.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>specify number of doses</td>
<td>83.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>vinblastine (VLB, Velban)</td>
<td>84.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>vinorelbine (Navelbine)</td>
<td>85.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>zoledronic acid (Zometa)</td>
<td>86.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>other systemic therapy</td>
<td>87.</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>specify other therapy</td>
<td>88.</td>
<td>1 yes  2 no</td>
</tr>
</tbody>
</table>

Radiation Therapy: 89.  | 1 yes  2 no  cont. w/ q. 97  | 151.  | 1 yes  2 no  cont. w/ q. 159 |
| Date therapy started: | 90.  | Month  Day  Year  | 152.  | Month  Day  Year  |
| Date therapy stopped: | 91.  | Month  Day  Year  | 153.  | Month  Day  Year  |
| Local / regional | 92.  | 1 yes  2 no  cont. w/ q. 94  | 154.  | 1 yes  2 no  cont. w/ q. 156 |
| Specify total dose: | 93.  | cGy (rads) 155.  | cGy (rads)  |
| Other radiotherapy site | 94.  | 1 yes  2 no  cont. w/ q. 97  | 156.  | 1 yes  2 no  cont. w/ q. 159 |
| Specify other radiation site | 95.  | 1 yes  2 no  | 157.  | 1 yes  2 no  |
| Specify total dose: | 96.  | cGy (rads) 158.  | cGy (rads)  |
### 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
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. Cell culture technique
   179. Immunohistochemistry (IHC)
   180. Polymerase chain reaction (PCR)
   181. Routine histopathology
   182. 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. Cell culture technique
   186. Immunohistochemistry (IHC)
   187. Polymerase chain reaction (PCR)
   188. Routine histopathology
   189. Other method

190. Specify:

Specify all sites of disease involvement:

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

215. Specify other site:
### 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.)

<table>
<thead>
<tr>
<th>Number</th>
<th>Disease Status Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>complete response (CR) — disappearance of all target lesions for a period of at least one month</td>
</tr>
<tr>
<td>2</td>
<td>complete response with persistent imaging abnormalities of unknown significance (CRU)</td>
</tr>
<tr>
<td>3</td>
<td>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</td>
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<tr>
<td>4</td>
<td>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</td>
</tr>
<tr>
<td>5</td>
<td>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</td>
</tr>
<tr>
<td>6</td>
<td>not assessed</td>
</tr>
<tr>
<td>7</td>
<td>unknown / not tested</td>
</tr>
</tbody>
</table>

218. Specify reason: ____________________

219. Date of the most recent assessment for disease status prior to the preparative regimen: [Month] [Day] [Year]

220. Signed: ____________________

Person completing form

Please print name: ____________________

Phone: (___________) ____________________

Fax: (___________) ____________________

E-mail address: ____________________

Fax this form to your designated campus (Milwaukee 414-805-0714 or Minneapolis 612-627-5895).