Form 2020 R2.0: Breast Cancer Pre-HSCT Data

Key Fields

Sequence Number: ____________________________
Date Received: __ __ __ __ - __ __- __ __
CIBMTR Center Number: ____________________________
CIBMTR Recipient ID: ____________________________

Today's Date: __ __ __ __ - __ __- __ __
Date of HSCT for which this form is being completed: __ __ __ __ - __ __- __ __

HSCT Type (check all that apply):
- Autologous
- Allogeneic, unrelated
- Allogeneic, related
- Syngeneic (identical twin)

Product Type (check all that apply):
- Marrow
- PBSC
- Cord blood
- Other product

Specify: ____________________________

If this is a report of a second or subsequent transplant, check here and continue with question 117.

Disease Assessment at Diagnosis

Questions: 1 - 27

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 - T2 N1 M0 - or - T2 N0 M0 - or - T3 N0 M0
   - IIIA - T3 N2 M0 - or - T3 N1 M0
   - IIIB - T4 N0 M0, T4 N0 M0, inflammatory
   - IV - T4 N0 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?
   - pre-menopausal
   - post-menopausal
   - not applicable, male recipient
   - Unknown

9 Specify the recipient's age at menopause: __________________________

10 Were metastases (other than ipsilateral axillary lymph nodes) present at diagnosis?
    - yes
    - no
    - Unknown

   Specify site(s) of metastasis:

11 Bone
   - yes
   - no

12 Bone marrow
   - yes
   - no

13 Brain
   - yes
   - no

14 Chest wall
   - yes
   - no

15 Liver
   - yes
   - no

16 Lung
   - yes
   - no

17 Lymph nodes (not ipsilateral axillary)
   - yes
   - no
**Specify lymph nodes:**

<table>
<thead>
<tr>
<th>Node</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 Contralateral internal mammary nodes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>19 Mediastinum</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 Subclavicular</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21 Supraclavicular</td>
<td></td>
<td></td>
</tr>
<tr>
<td>22 Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**23 Specify:**

- **Skin**
  - Yes
  - No

**25 Other site**

- Yes
  - No

**26 Specify site:**

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

- Yes
  - No

---

**Tumor and Lymph Node Assessment at Diagnosis**

**Questions: 28 - 53**

**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):**

- Known
  - Not known

29 Not measurable __________ cm

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

- Known
  - Not known

31 Not measurable __________ cm

**32 Pathologic size of the primary tumor (at the time of surgery):**

- Known
  - Not known

33 Not measurable __________ cm

**34 Was the primary tumor multicentric?**

- Yes
  - No
  - Unknown

**35 Was sentinel lymph node mapping performed?**

- Yes
  - No
36 Were axillary nodes examined by any method?
   - [ ] yes
   - [ ] no

37 Specify the number of axillary nodes examined:

38 How many axillary nodes were positive for breast cancer?
   - [ ] Known
   - [ ] Not known

39 Number of nodes:

40 Were estrogen receptor assays performed?
   - [ ] yes
   - [ ] no
   - [ ] Unknown

41 Specify estrogen receptor assay results:
   - [ ] Positive
   - [ ] Negative
   - [ ] borderline
   - [ ] Unknown

42 Specify percentage of positive estrogen receptors: ____________________ %

43 Were progesterone receptor assays performed?
   - [ ] yes
   - [ ] no
   - [ ] Unknown

44 Specify progesterone receptor assay results:
   - [ ] Positive
   - [ ] Negative
   - [ ] borderline
   - [ ] Unknown

45 Specify percentage of positive progesterone receptors: ____________________ %

46 Was the breast cancer tissue or a blood sample assessed for the Her-2/neu oncogene?
   - [ ] yes
   - [ ] no
   - [ ] Unknown

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

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

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

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

51 Was the proliferative index of the breast cancer quantified?
   - [ ] yes
   - [ ] no
   - [ ] Unknown

52 Specify the proliferative index value: ____________________ %
### Form 2020 R2.0: Breast Cancer Pre-HSCT Data

**Pre-HSCT Treatment for Breast Cancer**

Questions: 54 - 116

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

<table>
<thead>
<tr>
<th></th>
<th>yes</th>
<th>no</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

**Pre-HSCT BC Therapy Multiple (1)**

Questions: 55 - 116

<table>
<thead>
<tr>
<th>Line of Therapy:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Systemic Therapy:</td>
<td>yes</td>
<td>no</td>
</tr>
</tbody>
</table>

Date therapy started: __ __ __ __ - __ __ __ __

Date therapy stopped: __ __ __ __ - __ __ __ __

Number of cycles unknown / not applicable. Cycles: ________________

Was therapy given prior to any surgery (neoadjuvant)?

<table>
<thead>
<tr>
<th></th>
<th>yes</th>
<th>no</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

5-fluorouracil (5-FU, Adrucil)

<table>
<thead>
<tr>
<th></th>
<th>yes</th>
<th>no</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Anastrozole (Arimidex)

<table>
<thead>
<tr>
<th></th>
<th>yes</th>
<th>no</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

bevacizumab (Avastin)

<table>
<thead>
<tr>
<th></th>
<th>yes</th>
<th>no</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

capcitabine (Xeloda)

<table>
<thead>
<tr>
<th></th>
<th>yes</th>
<th>no</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Cisplatin (Platinol, CDDP)

<table>
<thead>
<tr>
<th></th>
<th>yes</th>
<th>no</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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53 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
<table>
<thead>
<tr>
<th></th>
<th>Name of Drug</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>65</td>
<td>cyclophosphamide (CTX)</td>
<td>yes/no</td>
</tr>
<tr>
<td>66</td>
<td>Daunorubicin (Cerubidine)</td>
<td>yes/no</td>
</tr>
<tr>
<td>67</td>
<td>Daunorubicin liposomal</td>
<td>yes/no</td>
</tr>
<tr>
<td>68</td>
<td>docetaxel (Taxotere)</td>
<td>yes/no</td>
</tr>
<tr>
<td>69</td>
<td>Doxorubicin (Adriamycin)</td>
<td>yes/no</td>
</tr>
<tr>
<td>70</td>
<td>Doxorubicin liposomal (Doxil)</td>
<td>yes/no</td>
</tr>
<tr>
<td>71</td>
<td>epirubicin (Ellence)</td>
<td>yes/no</td>
</tr>
<tr>
<td>72</td>
<td>exemestane (Aromasin)</td>
<td>yes/no</td>
</tr>
<tr>
<td>73</td>
<td>Gemcitabine (Gemzar)</td>
<td>yes/no</td>
</tr>
<tr>
<td>74</td>
<td>Goserelin acetate (Zoladex)</td>
<td>yes/no</td>
</tr>
<tr>
<td>75</td>
<td>Idarubicin (Idamycin)</td>
<td>yes/no</td>
</tr>
<tr>
<td>76</td>
<td>Lapatinib (Tykerb)</td>
<td>yes/no</td>
</tr>
<tr>
<td>77</td>
<td>Letrozole (Femara)</td>
<td>yes/no</td>
</tr>
<tr>
<td>78</td>
<td>Megestrol (Megace)</td>
<td>yes/no</td>
</tr>
<tr>
<td>79</td>
<td>methotrexate (MTX, Folex)</td>
<td>yes/no</td>
</tr>
<tr>
<td>80</td>
<td>Mitoxantrone (Novantrone)</td>
<td>yes/no</td>
</tr>
<tr>
<td>81</td>
<td>Paclitaxel (Abraxane, Taxol)</td>
<td>yes/no</td>
</tr>
</tbody>
</table>
### Form 2020 R2.0: Breast Cancer Pre-HSCT Data

<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>Description</th>
<th>Yes</th>
<th>No</th>
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</thead>
<tbody>
<tr>
<td>82</td>
<td>Pamidronate (Aredia)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>83</td>
<td>tamoxifen (Nolvadex)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>84</td>
<td>thiotepa (Thioplex)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>85</td>
<td>Toremifene (Fareston)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>86</td>
<td>Trastuzumab (Herceptin)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>87</td>
<td>Specify number of doses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>88</td>
<td>vinblastine (VLB, Velban)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>89</td>
<td>vinorelbine (Navelbine)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>90</td>
<td>Zoledronic acid (Zometa)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>91</td>
<td>Other systemic therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>92</td>
<td>Specify other therapy:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>93</td>
<td>Radiation Therapy:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>94</td>
<td>Date therapy started:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>95</td>
<td>Date therapy stopped:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>96</td>
<td>Local / regional</td>
<td></td>
<td></td>
</tr>
<tr>
<td>97</td>
<td>Specify total dose:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>98</td>
<td>Other radiotherapy site</td>
<td></td>
<td></td>
</tr>
<tr>
<td>99</td>
<td>Specify other radiation site:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>100</td>
<td>Specify total dose:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>101</td>
<td>Surgery (not biopsy):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>102</td>
<td>Date of surgery:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
103 Lumpectomy
   yes  no

104 Mastectomy
   yes  no

105 Other surgery
   yes  no

106 Specify other surgery: 

107 Was recipient on a study?
   yes  no

108 Specify study: 

109 Was this line of therapy given for stem cell priming?
   yes  no

110 Non-Bone response code - Response Evaluation Criteria in Solid Tumors (RECIST):
   - complete remission (CR) — disappearance of all target lesions for a period of at least one month
   - complete response (CRU) with persistent imaging abnormalities of unknown significance
   - 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
   - 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
   - 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
   - not assessed (NA)
   - unknown/not tested

111 If non-bone is a CR was the complete response pathologically confirmed?
   yes  no

112 Bone response code: 

113 Date response established: __ __ __ __

114 Did disease relapse/progress following this line of therapy?
   yes  no

115 Date of relapse/progression: __ __ __ __

116 Specify site(s) of relapse/progression: 

Most Recent Disease Assessment Prior to the Start of the Preparative Regimen
Questions: 117 - 158

117 Was a bone marrow biopsy performed prior to the preparative regimen (high-dose therapy)?
   yes  no

118 Date of most recent bone marrow biopsy: __ __ __ __
### 119 Was breast cancer present?
- [ ] yes
- [x] no

#### Specific detection method and result:

<table>
<thead>
<tr>
<th>Method</th>
<th>Positive</th>
<th>Negative</th>
<th>Not tested</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>120 Cell culture technique</strong></td>
<td>[ ]</td>
<td>[x]</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>121 Immunohistochemistry (IHC)</strong></td>
<td>[ ]</td>
<td>[x]</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>122 Polymerase chain reaction (PCR)</strong></td>
<td>[ ]</td>
<td>[x]</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>123 Routine histopathology</strong></td>
<td>[ ]</td>
<td>[x]</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>124 other method</strong></td>
<td>[ ]</td>
<td>[x]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

**125 Specify:**

### 126 Did the recipient ever have bone marrow involvement with breast cancer (other than the involvement indicated at question 117?)
- [ ] yes
- [ ] no

#### Specify detection method and result:

<table>
<thead>
<tr>
<th>Method</th>
<th>Positive</th>
<th>Negative</th>
<th>Not tested</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>127 Cell culture technique</strong></td>
<td>[ ]</td>
<td>[x]</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>128 Immunohistochemistry (IHC)</strong></td>
<td>[ ]</td>
<td>[x]</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>129 Polymerase chain reaction (PCR)</strong></td>
<td>[ ]</td>
<td>[x]</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>130 Routine histopathology</strong></td>
<td>[ ]</td>
<td>[x]</td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>131 Other method</strong></td>
<td>[ ]</td>
<td>[x]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

**132 Specify:**

### Specify all sites of disease involvement:

Present at any time between diagnosis and HSCT? (questions 133-144)

<table>
<thead>
<tr>
<th>Site</th>
<th>Present</th>
<th>Absent</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>133 Bone - radiographic</strong></td>
<td>[ ]</td>
<td>[x]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

*Mail, fax or email this form to Minneapolis. Fax: 612-627-5895. Email: scanform@nmdp.org. Retain the original form at the transplant center.*
<table>
<thead>
<tr>
<th>Question</th>
<th>Tumor Site</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>134</td>
<td>Bone - symptomatic</td>
<td></td>
<td></td>
<td>Unknown</td>
</tr>
<tr>
<td>135</td>
<td>Brain</td>
<td></td>
<td></td>
<td>Unknown</td>
</tr>
<tr>
<td>136</td>
<td>Breast</td>
<td></td>
<td></td>
<td>Unknown</td>
</tr>
<tr>
<td>137</td>
<td>Chest wall</td>
<td></td>
<td></td>
<td>Unknown</td>
</tr>
<tr>
<td>138</td>
<td>Liver</td>
<td></td>
<td></td>
<td>Unknown</td>
</tr>
<tr>
<td>139</td>
<td>Lung</td>
<td></td>
<td></td>
<td>Unknown</td>
</tr>
<tr>
<td>140</td>
<td>Axillary lymph nodes</td>
<td></td>
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<td>Unknown</td>
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<td>141</td>
<td>Other lymph nodes</td>
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<td>Unknown</td>
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<tr>
<td>142</td>
<td>Pleura</td>
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<td>143</td>
<td>Skin</td>
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<td>144</td>
<td>Other</td>
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<td>Unknown</td>
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<td>145</td>
<td>Bone-radiographic</td>
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<td></td>
<td>Unknown</td>
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<tr>
<td>146</td>
<td>Bone - symptomatic</td>
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<td></td>
<td>Unknown</td>
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<tr>
<td>147</td>
<td>Brain</td>
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<td>Unknown</td>
</tr>
<tr>
<td>148</td>
<td>Breast</td>
<td></td>
<td></td>
<td>Unknown</td>
</tr>
</tbody>
</table>

Present immediately prior to the start of the preparative regimen? (questions 145-156)

**Form 2020 R2.0: Breast Cancer Pre-HSCT Data**

**Center:**

**CRID:**
Chest wall
149

Liver
150

Lung
151

Axillary lymph nodes
152

Other lymph nodes
153

Pleura
154

Skin
155

Other
156

Question 157 should be answered if questions 144 and/or 156 were answered Yes.

157 Specify other site: ____________________________

158 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.)

- sensitive - response to platinum with ≥ 50% reduction in bidimensional diameter of all disease sites with no new sites of disease
- resistant - <50% reduction in diameter of all disease sites or development of new disease sites
- untreated/last line of therapy was surgery or radiation, not chemotherapy
- Unknown
- chemotherapy was only given as adjuvant to the primary surgery or radiation therapy
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.)

- complete remission (CR) — disappearance of all target lesions for a period of at least one month
- complete response (CRU) with persistent imaging abnormalities of unknown significance
- 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
- 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
- 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
- not assessed (NA)
- unknown/not tested

Specify reason: ____________________________

Date of the most recent assessment for disease status prior to the preparative regimen: __ __ __ __ - __ __ __ __

First Name: ____________________________  Last Name: ____________________________

Phone number: ____________________________  Fax number: ____________________________

E-mail address: ____________________________