

ERROR CORRECTION FORM

Sequence Number:

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CIBMTR Recipient ID:

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Visit:

100 day
 6 month

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 year

Today's Date:

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| Month | Day | Year | | | | | | | | | | | | | | | | | |

Infusion Date:

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| Month | Day | Year | | | | | | | | | | | | | | | | | |

CIBMTR Center Number:

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Initials:

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Testicular / Germ Cell Cancer Post-HSCT Data

Registry Use Only

Sequence Number:

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Date Received:

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Today's Date:

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| | | | | | | | | | | | | | | | | | | | |
| Month | Day | Year | | | | | | | | | | | | | | | | | |

Date of HSCT for which this form is being completed:

| | | | | | | | | | | | | | | | | | | | |
|-------|-----|------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
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| Month | Day | Year | | | | | | | | | | | | | | | | | |

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

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

Visit: 100 day 6 month 1 year 2 years > 2 years, specify:

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To be completed in conjunction with a Form 2100 – 100 Days Post-HSCT Data, Form 2200 – Six Months to Two Years Post-HSCT Data, or Form 2300 – Yearly Follow-Up for Greater Than Two Years Post-HSCT Data. Information reported here should reflect the date of last contact as reported in the post-HSCT data collection form, or immediately prior to death.

Disease Assessment at the Time of Best Response to HSCT

Best response is based on response to the HSCT, but does NOT include response to any therapy given for disease relapse or progression post-HSCT. When determining the best response to HSCT, compare the post-HSCT disease status to the status immediately prior to the preparative regimen, regardless of time since HSCT. This comparison is meant to capture the BEST disease status in response to HSCT that occurred in the reporting interval, even if a subsequent disease relapse or progression occurred during the same reporting interval. If a recipient already achieved their best response in a previous reporting interval, confirm the best response and check the box to indicate "date previously reported."

- Compared to the disease status prior to the preparative regimen, what was the best response to HSCT since the date of the last report? (Include response to any post-HSCT treatment planned as of Day 0.)
 - continued complete response (CCR) – continued absence of all disease after a complete response to a previous line of therapy
 - complete response (CR) – absence of clinically detectable disease including normal HCG and AFP and normalization of previously abnormal radiographic studies for at least one month
 - partial response (PR) – $\geq 50\%$ reduction in the sum of the perpendicular diameters of measurable lesions for ≥ 1 month and/or $\geq 50\%$ reduction in tumor markers
 - stable disease (SD) – tumor regression not fulfilling the requirement for partial response or tumor progression $< 25\%$ increase in the bidimensionally measurable tumor parameters
 - no response (NR) – $< 50\%$ reduction in disease or tumor markers
 - progressive disease (PD) – new lesions that prove to be viable cancer and/or rise in the pre-treatment tumor markers and/or $> 25\%$ increase in measurable lesions that are related to progressive viable cancer
 - markers elevated (ME) – no measurable disease, but tumor markers elevated
 - not evaluable, toxic death (NETD)

2. Date the best response first began:

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 date of best response was previously reported

3. Was the response documented surgically?

- yes
- no
- unknown

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Visit:

- 100 day
 6 month
 year

Today's Date:

/ /
Month Day Year

Infusion Date:

/ /
Month Day Year

CIBMTR Center Number:

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Relapse or Progression Post-HSCT

4. Has the disease relapsed or progressed since the date of the last report?

- 1 yes
2 no
3 unknown

5. Date of progression / relapse: / /
Month Day Year date unknown

6. *Allogeneic HSCTs only*: Was there subsequent disease stability or regression without further therapy (so-called graft-versus-tumor effect)?

- 1 yes
2 no
3 unknown

7. Did this change in disease status qualify as a partial response or better if compared to a post-HSCT imaging study? (see page 1 for criteria to define partial response)

- 1 yes
2 no

8. Date of response:

/ /
Month Day Year

date unknown

Specify site(s) of disease progression / recurrence:

9. 1 yes 2 no 3 unknown Central nervous system
10. 1 yes 2 no 3 unknown Liver – parenchymal
11. 1 yes 2 no 3 unknown Lung
12. 1 yes 2 no 3 unknown Lymph nodes – distant
13. 1 yes 2 no 3 unknown Lymph nodes – regional
14. 1 yes 2 no 3 unknown Pelvis
15. 1 yes 2 no 3 unknown Pleura
16. 1 yes 2 no 3 unknown Tumor markers (AFP, HCG, LDH)
17. 1 yes 2 no 3 unknown Other site →

18. Specify site: _____

Post-HSCT Planned Treatment for Testicular Cancer

19. Was planned treatment given per protocol since the date of the last report? (Include any maintenance therapy, but exclude any treatment for relapse / progressive disease.)

- 1 yes
2 no

20. Was surgical resection performed for persistent radiographic abnormalities?

- 1 yes
2 no

21. Specify date of surgery: / /
Month Day Year

22. Specify type of surgery:

- 1 biopsy only (not debulking)
2 debulking
3 orchiectomy only
4 removal of extra-abdominal metastatic lesion
5 unilateral retroperitoneal node dissection and orchiectomy
6 other type of surgery →

23. Specify surgery: _____

24. Was the extent of the resection confirmed radiographically?

- 1 yes
2 no
3 unknown

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Visit:

- 100 day
 6 month

 year

Today's Date:

| | | | | | |
|-------|-----|------|---|--|--|
| | | 2 | 0 | | |
| Month | Day | Year | | | |

Infusion Date:

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| | | 2 | 0 | | |
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25. Was any persistent, viable tumor detected?

- 1 yes
 2 no
 3 unknown

26. Was radiation therapy given?

- 1 yes →
 2 no

27. Specify date radiation started:

| | | | | | |
|-------|-----|------|---|--|--|
| | | 2 | 0 | | |
| Month | Day | Year | | | |

28. Specify date radiation stopped:

| | | | | | |
|-------|-----|------|---|--|--|
| | | 2 | 0 | | |
| Month | Day | Year | | | |

Specify the radiation field(s):

29. 1 yes 2 no Pelvis → 30. Total dose:

 cGy (rads)

31. 1 yes 2 no Total abdomen → 32. Total dose:

 cGy (rads)

33. 1 yes 2 no Other site → 34. Specify field: _____

35. Total dose:

 cGy (rads)

36. Was chemotherapy / immunotherapy given?

- 1 yes →
 2 no

37. Specify date therapy started:

| | | | | | |
|-------|-----|------|---|--|--|
| | | 2 | 0 | | |
| Month | Day | Year | | | |

38. Specify date therapy stopped:

| | | | | | |
|-------|-----|------|---|--|--|
| | | 2 | 0 | | |
| Month | Day | Year | | | |

Specify systemic treatment(s):

39. 1 yes 2 no aldesleukin (interleukin-2)
 40. 1 yes 2 no altretamine (Hexalen)
 41. 1 yes 2 no bleomycin (BLM, Blenoxane)
 42. 1 yes 2 no carboplatin (Paraplatin)
 43. 1 yes 2 no cisplatin (CDDP, Platinol)
 44. 1 yes 2 no cyclophosphamide (CTX)
 45. 1 yes 2 no dactinomycin (Cosmegen)
 46. 1 yes 2 no doxorubicin (Adriamycin)
 47. 1 yes 2 no doxorubicin liposomal (Doxil)
 48. 1 yes 2 no etoposide (VP-16, VePesid)
 49. 1 yes 2 no gemcitabine (Gemzar)
 50. 1 yes 2 no ifosfamide (Ifex)
 51. 1 yes 2 no mitoxantrone (Novantrone)
 52. 1 yes 2 no methotrexate (MTX, Folex)
 53. 1 yes 2 no paclitaxel (Taxol)
 54. 1 yes 2 no thiotepa (Thioplex)
 55. 1 yes 2 no vinblastine (Velban, VLB)
 56. 1 yes 2 no other

therapy → 57. Specify treatment: _____

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 / /
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Most Recent Laboratory Studies Post-HSCT

Specify the results of any imaging studies performed for the following disease sites since the date of the last report:

58. 1 disease present 2 disease absent 3 not tested Abdomen — CT
59. 1 disease present 2 disease absent 3 not tested Bone — bone scan
60. 1 disease present 2 disease absent 3 not tested Bone — CT
61. 1 disease present 2 disease absent 3 not tested Bone — MRI
62. 1 disease present 2 disease absent 3 not tested Bone — x-ray
63. 1 disease present 2 disease absent 3 not tested Chest — CT
64. 1 disease present 2 disease absent 3 not tested Chest — x-ray
65. 1 disease present 2 disease absent 3 not tested Head — CT
66. 1 disease present 2 disease absent 3 not tested Head — MRI
67. 1 disease present 2 disease absent 3 not tested Pelvis — CT
68. 1 disease present 2 disease absent 3 not tested PET scan

Specify the following tumor markers determined since the date of the last report:

69. Serum alpha-fetoprotein (AFP):

- 1 known → . ng/mL
2 not known

70. Serum beta-HCG (BHCG):

- 1 known → . IU/L
2 not known

71. LDH:

- 1 known → .
2 not known

Specify units:

- 1 U/L
2 μ kat/L

72. Other tumor marker?

- 1 yes →
2 no

73. Specify tumor marker: _____
74. Specify value: _____

Disease Status at the Time of Assessment for This Reporting Period

75. What is the current status of testicular cancer at the time of this report, or at the time of death?

- 1 complete response
2 not in complete response

76. Date the current disease status was established in this reporting period:

 / /
Month Day Year

77. Signed: _____

Person completing form

Please print name: _____

Phone number: (_____) _____

Fax number: (_____) _____

E-mail address: _____