Form 2540 R1.0: Tepadina® Supplemental Data Collection Form

Center: CRID:

Key Fields

Sequence Number: _____

Date Received: __ __ __ __ - __ __- __ __

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Event date: __ __ __ __ - __ __- __ __

Visit

○ 100 day ○ 6 months ○ 1 year ○ 2 years ○ > 2 years,

Specify: _____

Tepadina® Stop Date

Questions: 1 - 2

1 Tepadina® stop date

○ Known ○ Unknown

2 Date stopped: __ __ __ __ - __ __- __ __

Hematologic Findings at Day 7 Post-HCT

Questions: 3 - 13

3 Were blood counts tested at day 7? (post-HCT)

○ Yes ○ No

4 Date of blood count: __ __ __ __ - __ __- __ __

5 WBC

○ Known ○ Unknown

6 WBC: _____ ○ x 10^9/L (x 10^3/mm^3)

○ x 10^6/L

7 Neutrophils

○ Known ○ Unknown

8 Neutrophils: _____ %

9 Hemoglobin

○ Known ○ Unknown

10 Hemoglobin: _____ ○ g/dL ○ g/L ○ mmol/L

11 Platelets

○ Known ○ Unknown

12 Platelets: _____ ○ x 10^9/L (x 10^3/mm^3)

○ x 10^6/L

13 Were platelets transfused ≤ 7 days before date of test?

○ Yes ○ No

Hematologic Findings at Day 14 Post-HCT

Questions: 14 - 24

14 Were blood counts tested at day 14? (post-HCT)

○ Yes ○ No

15 Date of blood count: __ __ __ __ - __ __- __ __

16 WBC

○ Known ○ Unknown

17 WBC: _____ ○ x 10^9/L (x 10^3/mm^3)

○ x 10^6/L

18 Neutrophils

○ Known ○ Unknown

19 Neutrophils: _____ %

20 Hemoglobin

○ Known ○ Unknown

21 Hemoglobin: _____ ○ g/dL ○ g/L ○ mmol/L

22 Platelets

○ Known ○ Unknown

23 Platelets: _____ ○ x 10^9/L (x 10^3/mm^3)

○ x 10^6/L

24 Were platelets transfused ≤ 7 days before date of test?

○ Yes ○ No

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Center: CRID:

Hematologic Findings at Day 21 Post-HCT

Questions: 25 - 35

25 Were blood counts tested at day 21? (post-HCT)
○ Yes ○ No

26 Date of blood count: __ __ __ __ - __ __- __ __

27 WBC
○ Known ○ Unknown

28 WBC: _____ ○ x 10^9/L (x 10^3/mm^3) ○ x 10^6/L

29 Neutrophils
○ Known ○ Unknown

30 Neutrophils: _____ %

31 Hemoglobin
○ Known ○ Unknown

32 Hemoglobin: _____ ○ g/dL ○ g/L ○ mmol/L

33 Platelets
○ Known ○ Unknown

34 Platelets: _____ ○ x 10^9/L (x 10^3/mm^3) ○ x 10^6/L

35 Were platelets transfused ≤ 7 days before date of test?
○ Yes ○ No

Organ Function

Questions: 36 - 67

Report any disorder / impairment that can be directly attributed to Tepadina®

36 Did the recipient experience thiotepa related hypersensitivity reaction during HCT?
○ Yes ○ No

37 Date of onset: __ __ __ __ - __ __- __ __

38 Grade
○ 1 ○ 2 ○ 3 ○ 4

39 In the transplant physician's judgment, was the disorder / impairment a direct result of the Tepadina® administration?
○ Yes ○ No

Erythematous rash / toxic skin reactions

40 Did the recipient develop an erythematous rash / toxic skin reaction?
○ Yes ○ No

41 Date of onset: __ __ __ __ - __ __- __ __

42 Symptoms (check all that apply)
☐ Erythematous rash
☐ Flushing
☐ Photosensitivity
☐ Stevens-Johnson syndrome / Toxic epidermal necrolysis

43 In the transplant physician's judgment, was the disorder / impairment a direct result of the Tepadina® administration?
○ Yes ○ No

Liver function

44 Did the recipient experience grade 3-4 elevation of AST, ALT, and/or bilirubin?
○ Yes ○ No

45 Date of onset: __ __ __ __ - __ __- __ __

46 In the transplant physician's judgment, was the disorder / impairment a direct result of the Tepadina® administration?
○ Yes ○ No

Neurological

47 Leukoencephalopathy
○ Yes ○ No

48 Date of onset: __ __ __ __ - __ __- __ __

49 In the transplant physician's judgment, was the disorder / impairment a direct result of the Tepadina® administration?
○ Yes ○ No

50 Other neurological toxicity
○ Yes ○ No

51 Specify other neurological toxicity: _____

52 Date of onset: __ __ __ __ - __ __- __ __

53 In the transplant physician's judgment, was the disorder / impairment a direct result of the Tepadina® administration?

○ Yes ○ No

Psychiatric

54 Confusion / delirium

○ Yes ○ No

55 Date of onset: __ __ __ __ - __ __- __ __

56 In the transplant physician's judgment, was the disorder / impairment a direct result of the Tepadina® administration?

○ Yes ○ No

57 Hallucination

○ Yes ○ No

58 Date of onset: __ __ __ __ - __ __- __ __

59 In the transplant physician's judgment, was the disorder / impairment a direct result of the Tepadina® administration?

○ Yes ○ No

Vascular

60 Hemorrhage

○ Yes ○ No

61 Date of onset: __ __ __ __ - __ __- __ __

62 In the transplant physician's judgment, was the disorder / impairment a direct result of the Tepadina® administration?

○ Yes ○ No

63 Cerebral hemorrhage

○ Yes ○ No

64 Date of onset: __ __ __ __ - __ __- __ __

65 In the transplant physician's judgment, was the disorder / impairment a direct result of the Tepadina® administration?

○ Yes ○ No

Questions 66 - 67 refer to data reported on form 2100, please ensure data reported here matches with form 2100.

66 In the transplant physician's judgment, were any of the disorders / impairments reported on the form 2100 a direct result of the Tepadina® reported administration?

○ Yes

○ No

○ Not Applicable (none reported on 2100)

67 Specify (check all that apply)

- ☐ Acute renal failure requiring dialysis
- ☐ Bronchiolitis obliterans
- ☐ Congestive heart failure
- ☐ Cryptogenic organizing pneumonia (COP / BOOP)
- ☐ Deep vein thrombosis (DVT) / Pulmonary embolism (PE)
- ☐ Diffuse alveolar hemorrhage
- ☐ GVHD (acute or chronic)
- ☐ Hypertension (HTN) requiring therapy
- ☐ Infection
- ☐ Mucositis requiring therapy
- ☐ New malignancy
- ☐ Non-infectious interstitial pneumonitis (IPn or ARDS) / idiopathic pneumonia syndrome (IPS)
- ☐ VOD

First Name: _____

Last Name: _____

E-mail address: _____

Date: __ __ __ __ - __ __- __ __