CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Intravenous Busulfan Study — Supplemental Data

CIBMTR Center Number: ☐☐☐☐☐

CIBMTR Recipient ID: ☐☐☐☐☐☐☐☐☐☐

Today's Date: ☐☐ Month ☐☐ Day 2 0 ☐☐ 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 ☐ multiple cord blood units infused ☐ other product, specify: _____

Registry Use Only

Sequence Number:

Date Received:

This form should be completed for recipients selected as a case on the study when intravenous busulfan plus cyclophosphamide or fludarabine was used in the pre-HSCT preparative regimen, and where a CIBMTR form 2400 – Pre-Transplant Essential Data (pre-TED) was previously submitted.

If the recipient has active CNS leukemia at the time of HSCT as reported on the pre-HSCT disease-specific form, he / she will be removed from the study.

1. Busulfan was indicated on the pre-TED as being part of the planned preparative regimen per protocol. Was IV busulfan actually given?

1 ☐ yes →

Comparing what was reported on the pre-TED to the medical record, was the planned dosing conveyed accurately on the pre-TED? If not, please correct the pre-TED form (2400) in FormsNet or send a paper Error Correction form. The busulfan preparative regimen data reported on the pre-TED form and in question 2 of this form should match.

2. Specify the <u>total prescribed cumulative</u> dose for the preparative regimen (per protocol): ☐☐☐.☐

Specify units:
1 ☐ mg/m^2
2 ☐ mg/kg

3. How was the busulfan administration scheduled for the regimen?
1 ☐ every 6 hours
2 ☐ daily
3 ☐ twice daily
4 ☐ other schedule →

4. Specify other frequency of busulfan administration: _____

5. Specify planned <u>total</u> administration duration: ☐☐ total: 1 ☐ doses 2 ☐ days

2 ☐ no →

Please correct the pre-TED form (2400) in FormsNet or send a paper Error Correction form. Continue with the signature lines at question 14.

Internal use: Document number F00682 revision 1 Replaces: n/a

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

CIBMTR Center Number: | | | | | | CIBMTR Recipient ID: | | | | | | | | | | |

6. Were pharmacokinetics performed to determine preparative regimen drug dosing?

Comparing what was reported on the Form 2000 — Recipient Baseline Data at question 367 to the medical record, was pharmacokinetic testing conveyed accurately on the baseline form? If not, please correct the Baseline Form in FormsNet or send a paper Error Correction form.

1 ☐ yes →
2 ☐ no

Specify when pharmacokinetics were performed:

7. 1 ☐ yes 2 ☐ no Prior to administration of the preparative regimen with a test dose
8. 1 ☐ yes 2 ☐ no During administration of the preparative regimen
9. Specify the pharmacokinetic target level of busulfan: *(this information can typically be found within the recipient's treatment planner, face sheet, medical record, or PK requisition form)*

1 ☐ concentration steady-state plasma level (Css) →
10. Specify the busulfan Css target level: | | | | | ng / mL

2 ☐ area under the plasma concentration time curve (AUC) →
11. Specify the busulfan AUC target level: | | | | | µM x min

12. Was a plan in place to adjust the dose of IV busulfan based on the results of the pharmacokinetics?

1 ☐ yes →
2 ☐ no

13. Was the busulfan dose adjusted based on the pharmacokinetics?
1 ☐ yes
2 ☐ no

14. Signed: _____
Person completing form

Please print name: _____

Phone number: (_____) _____

Fax number: (_____) _____

E-mail address: _____

Internal use: Document number F00682 revision 1 Replaces: n/a