2509: Intravenous Busulfan Study - Supplemental Data

Registry Use Only
Sequence Number:

Date Received:

Key Fields

Sequence Number: _____ _____ _____ _____ _____ _____ _____
ELSE GOTO Date Received:

Date Received: __ ______' __ ' ____ _____
ELSE GOTO CIBMTR Center Number

CIBMTR Center Number: ________________
ELSE GOTO CIBMTR Recipient ID:

CIBMTR Recipient ID: ________________
ELSE GOTO Today's Date:

Today's Date: __ ______' __ ' ____ _____
ELSE GOTO Date of HSCT for which this form is being completed:

Date of HSCT for which this form is being completed: __ ______' __ ' ____ _____
ELSE GOTO Autologous

HSCT type (check all that apply):
☐ Autologous
ELSE GOTO Allogeneic, unrelated

☐ Allogeneic, unrelated
ELSE GOTO Allogeneic, related

☐ Allogeneic, related
ELSE GOTO Syngeneic (identical twin)
Syngeneic (identical twin)

ELSE GOTO Marrow

Product Type (check all that apply):

☐ Marrow
ELSE GOTO PBSC

☐ PBSC
ELSE GOTO Cord blood

☐ Cord blood
ELSE GOTO multiple cord blood units infused

☐ multiple cord blood units infused
ELSE GOTO Other product

☐ Other product

IF Other product:= checked
THEN GOTO Specify:

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

Specify:

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

Busulfan Dosing and Schedule

Questions: 1-5

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?

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.

O yes
O no

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

THEN GOTO (2) Specify the total prescribed cumulative dose for the preparative regimen (per protocol):
**ELSE GOTO First name**

2 Specify the total prescribed cumulative dose for the preparative regimen (per protocol):
   - mg/m²
   - mg/kg

   ELSE GOTO specify unit of measure for total busulfan given

   ELSE GOTO (3) How was the busulfan administration scheduled for the regimen?

3 How was the busulfan administration scheduled for the regimen?
   - every 6 hours
   - daily
   - twice daily
   - other schedule

   IF (3) How was the busulfan administration scheduled for the regimen?:= other schedule
   THEN GOTO (4) Specify other frequency of busulfan administration:

   ELSE GOTO (5) Specify planned total administration duration:

4 Specify other frequency of busulfan administration:
   ________________________________

   ELSE GOTO (6) Specify planned total administration duration:

5 Specify planned total administration duration:
   __________

   ELSE GOTO total:

   O doses
   O days

   ELSE GOTO (6) Were pharmacokinetics performed to determine preparative regimen drug dosing?

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### Pharmacokinetics Questions: 6-13

Comparing what was reported on the Form 2000 - Recipient Baseline Data as 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.

6 Were pharmacokinetics performed to determine preparative regimen drug dosing?
   - yes
   - no

   IF (6) Were pharmacokinetics performed to determine preparative regimen drug dosing?:= yes
   THEN GOTO (7) Prior to administration of the preparative regimen with a test dose

   ELSE GOTO First name

   Specify when pharmacokinetics were performed:

7 Prior to administration of the preparative regimen with a test dose
   - yes
   - no

   ELSE GOTO (8) During administration of the preparative regimen
8. During administration of the preparative regimen
   - [ ] yes
   - [ ] no
   ELSE GOTO (9) pharmacokinetic target level of busulfan

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)
   - [ ] concentration steady-state plasma level (Css)
   - [ ] area under the plasma concentration time curve (AUC)
   IF (9) pharmacokinetic target level of busulfan:= concentration steady-state plasma level (Css)
   THEN GOTO (10) Specify the busulfan Css target level:
   ELSE GOTO (11) Specify the busulfan AUC target level:

10. Specify the busulfan Css target level:
    [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] ng/mL
    ELSE GOTO (11) Specify the busulfan AUC target level:

11. Specify the busulfan AUC target level:
    [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] µM x min
    ELSE GOTO (12) Was a plan in place to adjust the dose of IV busulfan based on the results of the pharmacokinetics?

12. Was a plan in place to adjust the dose of IV busulfan based on the results of the pharmacokinetics?
   - [ ] yes
   - [ ] no
   IF (12) Was a plan in place to adjust the dose of IV busulfan based on the results of the pharmacokinetics?:= yes
   THEN GOTO (13) Was the busulfan dose adjusted based on the pharmacokinetics?
   ELSE GOTO First name

13. Was the busulfan dose adjusted based on the pharmacokinetics?
   - [ ] yes
   - [ ] no
   ELSE GOTO First name

First Name: _______________________
ELSE GOTO Last name

Last Name: _______________________
ELSE GOTO Phone:

Phone: _______________________
ELSE GOTO Fax:

Fax: _______________________
ELSE GOTO E-mail address:

E-mail address: _______________________
ELSE GOTO End of Form