



SPIRIT2

STI571 Prospective International Randomised Trial

Supplementary information for Data Newsletter Issue 1, September 2016
Visit 15 and early discontinuation eCRF completion guide

Upon reaching visit 15

Upon reaching visit 15

In addition to updating all adverse event and concurrent medication pages please complete the following pages:

1. Visit 15 – complete as you would any other visit
2. Patient Outcome Page – discontinuation reason will be ‘study finished’

Patient Outcome - Browse

[Modify](#) | [Un-dock Window](#) | [Audit Trail](#) | [Print](#)

Why did patient permanently discontinue treatment?

STUDY FINISHED

If treatment failure, please select one of the following:

If more than one option applies please select the highest option on the list. (eg. For a patient who has lost a MCR and gone into Blast Crisis - Choose "Blast Crisis")

Please use the *Intolerance - Laboratory toxicity* option for neutropenia, thrombocytopenia, raised liver functions tests - without clinical signs and symptoms

If treatment failure, please enter Date of treatment failure/death

If other, please enter Other reason text

If protocol violator, please enter Reason for protocol violation

Comments

Navigate back to the Data Entry grid for Patient Z5003/0036

GO

Select 'study finished'

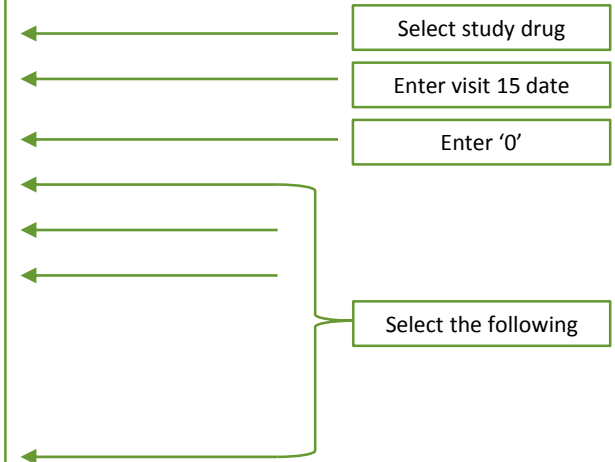
Upon reaching visit 15

3. Study drug log – add entry for study drug completion

a) Imatinib patients and,
 Dasatinib patients not continuing to receive study dasatinib

Study Drug - Data Entry (0)
Print

Study Drug	- Please Select - Imatinib Dasatinib
Change Date	
Dose	<input type="text"/>
Units	Mg <input type="button" value="v"/>
Frequency	ONCE PER DAY [OD] <input type="button" value="v"/>
Reason for change	Study drug permanently discontinued <input type="button" value="v"/>
If study drug permanently discontinued please complete Patient Outcome Page	
If "Other" please describe	<input style="width: 100%;" type="text"/>
If study drug permanently discontinued will the annual follow-up visits be completed for the study?	No [N] <input type="button" value="v"/>
Comments:	<input style="width: 100%;" type="text"/>



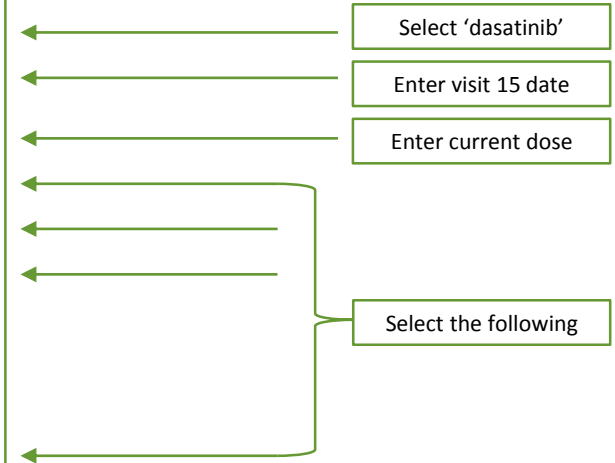
Upon reaching visit 15

3. Study drug log – add entry for study drug completion

b) Dasatinib patients – continuing to receive study dasatinib after visit 15

Study Drug - Data Entry (0) Print

Study Drug	Dasatinib
Change Date	
Dose	
Units	Mg
Frequency	ONCE PER DAY [OD]
Reason for change	Study drug permanently discontinued
If study drug permanently discontinued please complete Patient Outcome Page	
If "Other" please describe	
If study drug permanently discontinued will the annual follow-up visits be completed for the study?	No [N]
Comments:	



Early discontinuation

Early discontinuation

In addition to updating all adverse event and concurrent medication pages, for patients that discontinued study drug before visit 15, please complete the following pages:

1. Patient Outcome Page
 - a) Discontinuation reason

Patient Outcome - Data Entry
Print

Why did patient permanently discontinue treatment?

If treatment failure, please select one of the following:

If more than one option applies please select the highest option on the list. (eg. For lost a MCR and gone into Blast Crisis - Choose "Blast Crisis")

Please use the *Intolerance - Laboratory toxicity* option for neutropenia, thrombocytopenia, raised liver functions tests - without clinical signs and symptoms

If treatment failure, please enter Date of treatment failure/death

If other, please enter Other reason text

If protocol violator, please enter Reason for protocol violation

Comments

Select discontinuation reason

If you are unsure which option to select, please contact the trial office for advice.

Early discontinuation

b) Treatment failure reason

Patient Outcome - Data Entry
Print

Why did patient permanently discontinue treatment? - Please Select - ▾

If treatment failure, please select one of the following:

If more than one option applies please select the highest lost a MCR and gone into Blast Crisis - Choose "Blast Crisis"

Please use the *Intolerance - Laboratory toxicity* option for functions tests - without clinical signs and symptoms

If treatment failure, please enter Date of treatment failure/death

If other, please enter Other reason text

If protocol violator, please enter Reason for protocol violation

Comments

Cancel
Next

- Please Select -

- Death: non-CML related
- Death: CML-related
- Disease progression - blast crisis
- Disease progression - accelerated phase
- Loss of CHR (complete haematological response)
- Loss of MCR (major cytogenetic response)
- Intolerance - AE
- Intolerance - Laboratory toxicity
- Failure to achieve CHR after 6 months treatment
- Failure to achieve MCR after 12 months treatment
- Failure to achieve CCR after 24 months treatment

If treatment failure please select

Where the treatment failure reason is 'Intolerance – Laboratory toxicity', please ensure there is a corresponding lab result.

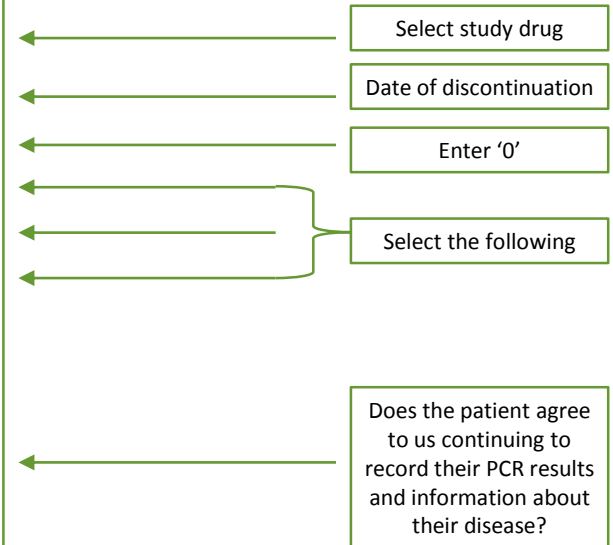
Where the treatment failure reason is 'Death' or 'Intolerance – AE', please ensure there is a corresponding AE recorded.

Early discontinuation

2. Study drug log page

Study Drug - Data Entry (0) Print

Study Drug	- Please Select -
Change Date	
Dose	0
Units	Mg
Frequency	ONCE PER DAY [OD]
Reason for change	Study drug permanently discontinued
If study drug permanently discontinued please complete Patient Outcome Page	
If "Other" please describe	
If study drug permanently discontinued will the annual follow-up visits be completed for the study?	- Please Select - Yes [Y] No [N]
Comments:	



Early discontinuation

3. Annual review pages

- ☞ If the patient agrees to annual follow up, these pages should be completed annually on the anniversary of the patient's randomisation until when the patient reaches 5 years from randomisation
- ☞ Annual visits will coincide with when the patient would have been due for visits 7, 9, 11, 13 and 15

Annual Review for Patients who have permanently Discontinued Study Treatment - Data Entry (0) [Print](#)

Date of annual review

Has patient's CML progressed since last assessment?

Current CML therapy	If other please state	
<input type="text" value="- Please Select -"/>	<input type="text"/>	<input type="checkbox"/>
<< Add a new row >>		

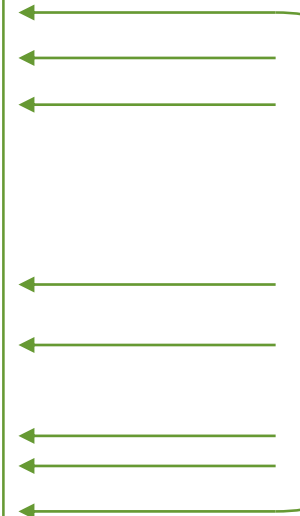
Has patient been diagnosed with another malignancy (including haematological) since last assessment?

If yes, give details

Is the patient still alive?

Date of death

Comments



Complete as much follow up information as possible

If the patient has received more than one treatment throughout the year, please add details of all treatments by adding a new row