SPIRIT 2

STI571 Prospective International Randomised Trial

Supplementary information for Data Newsletter Issue 1, September 2016

Visit 15 and early discontinuation eCRF completion guide

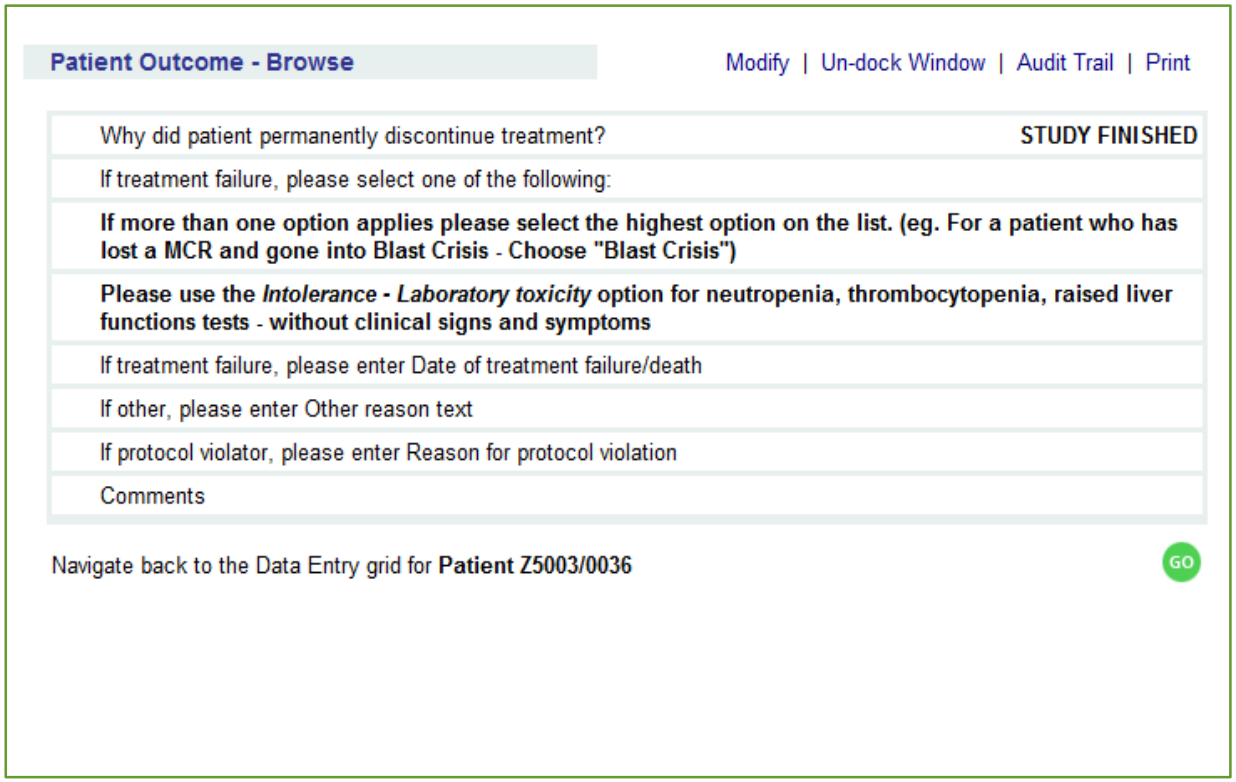
Upon reaching visit 15

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'

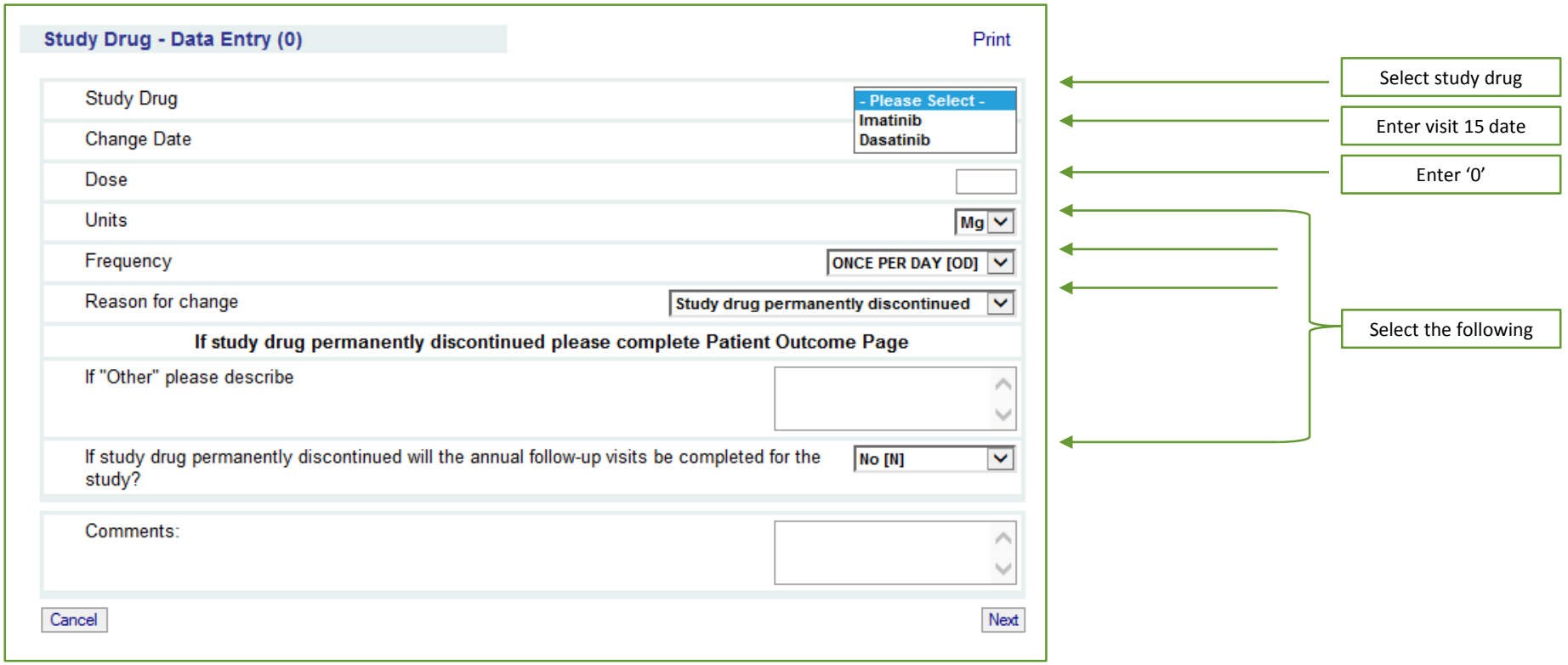


Select 'study finished'

Upon reaching visit 15

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

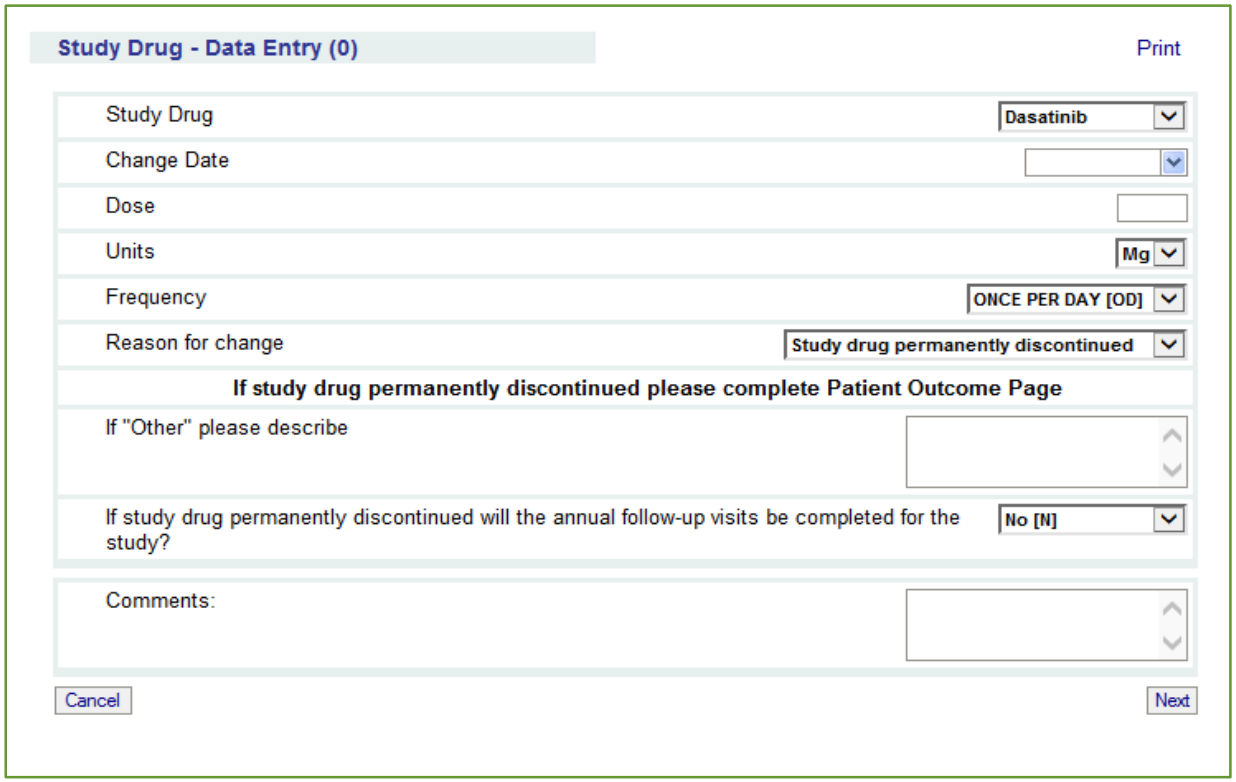
a) Imatinib patients and,
Dasatinib patients not continuing to receive study dasatinib



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



Select 'dasatinib'

Enter visit 15 date

Enter current dose

Select the following

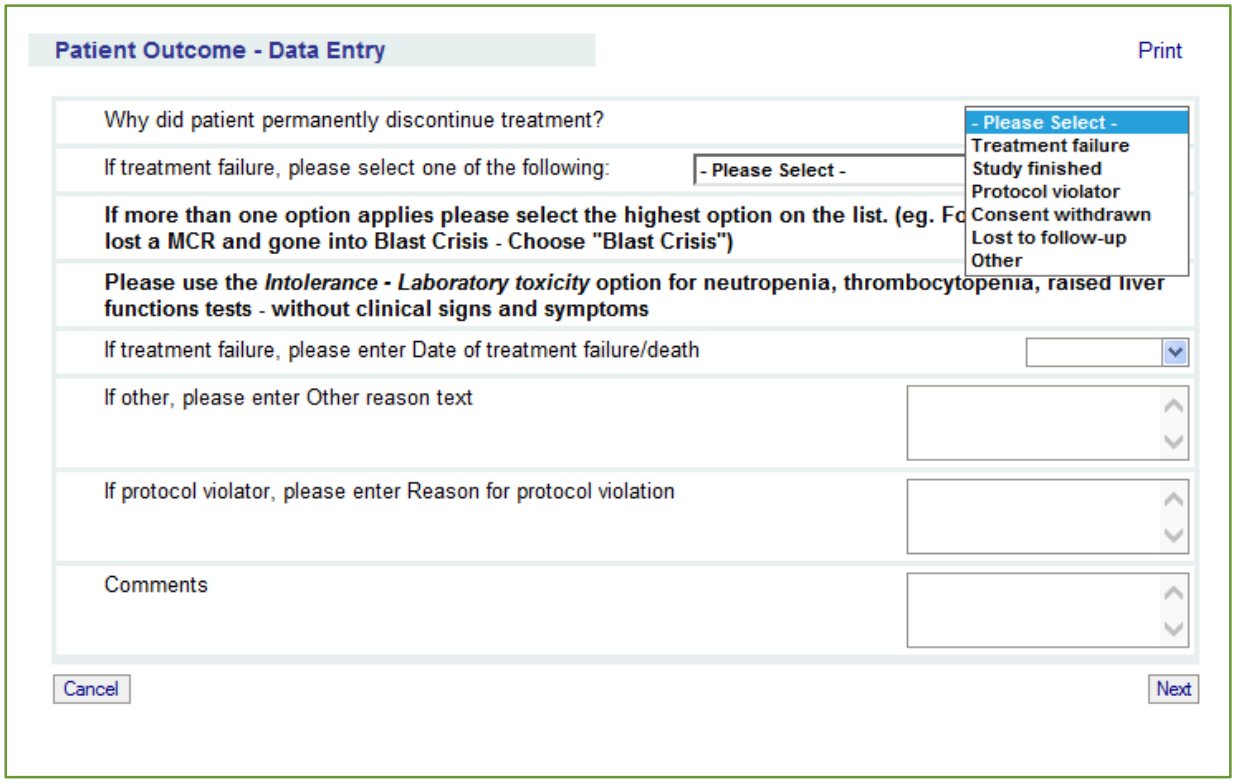
Early discontinuation

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

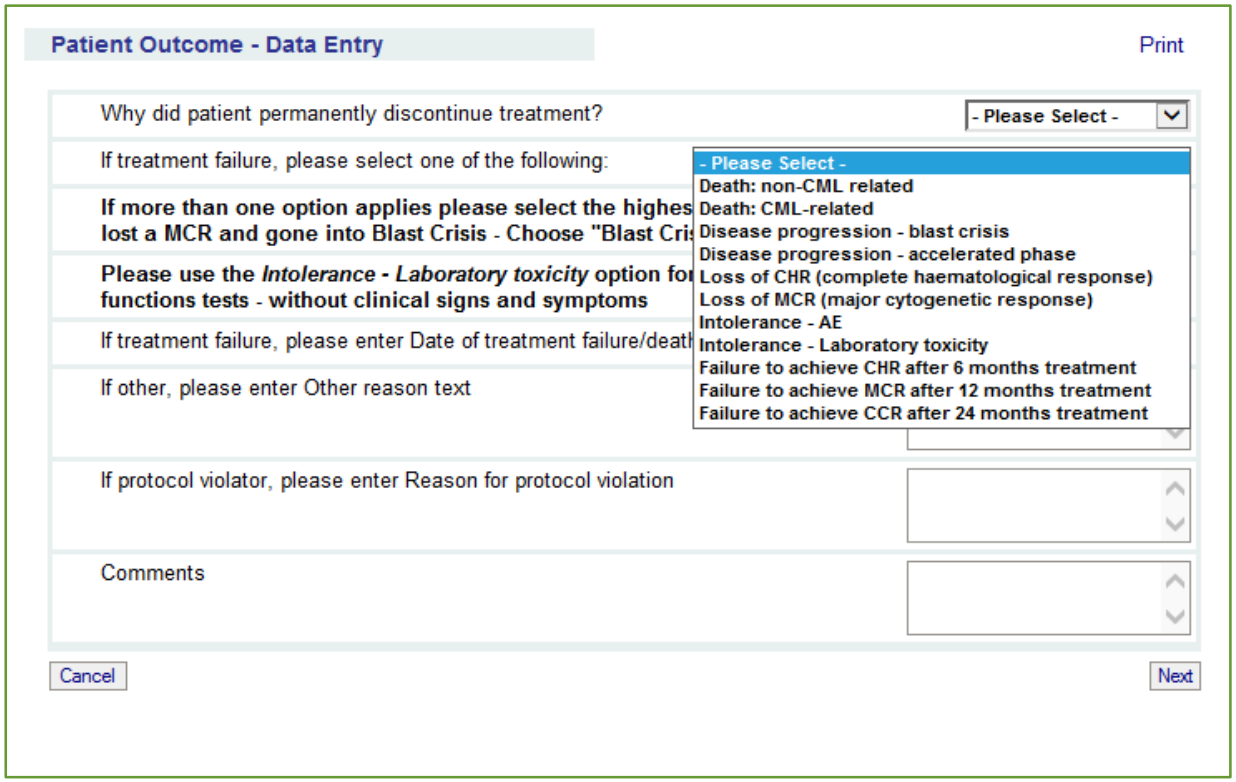


Select discontinuation reason

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

Early discontinuation

b) Treatment failure reason



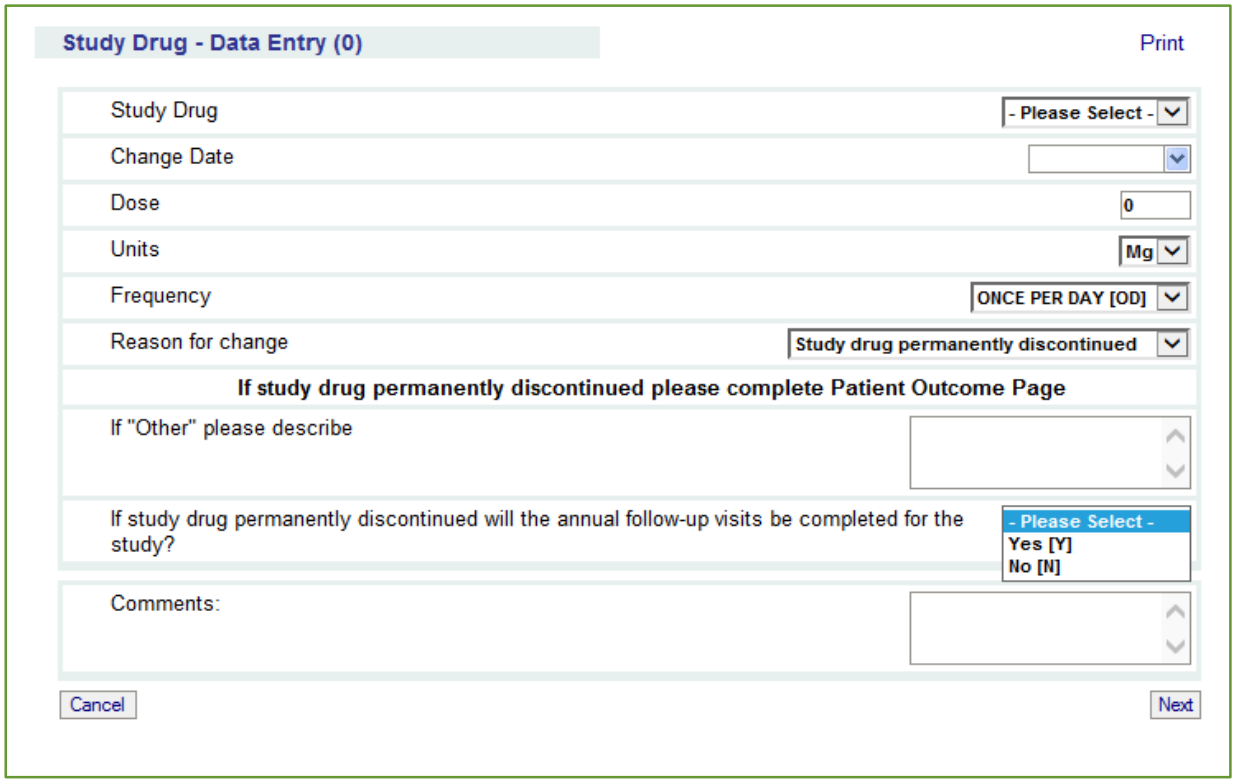
If treatment failure please select

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



Select study drug

Date of discontinuation

Enter '0'

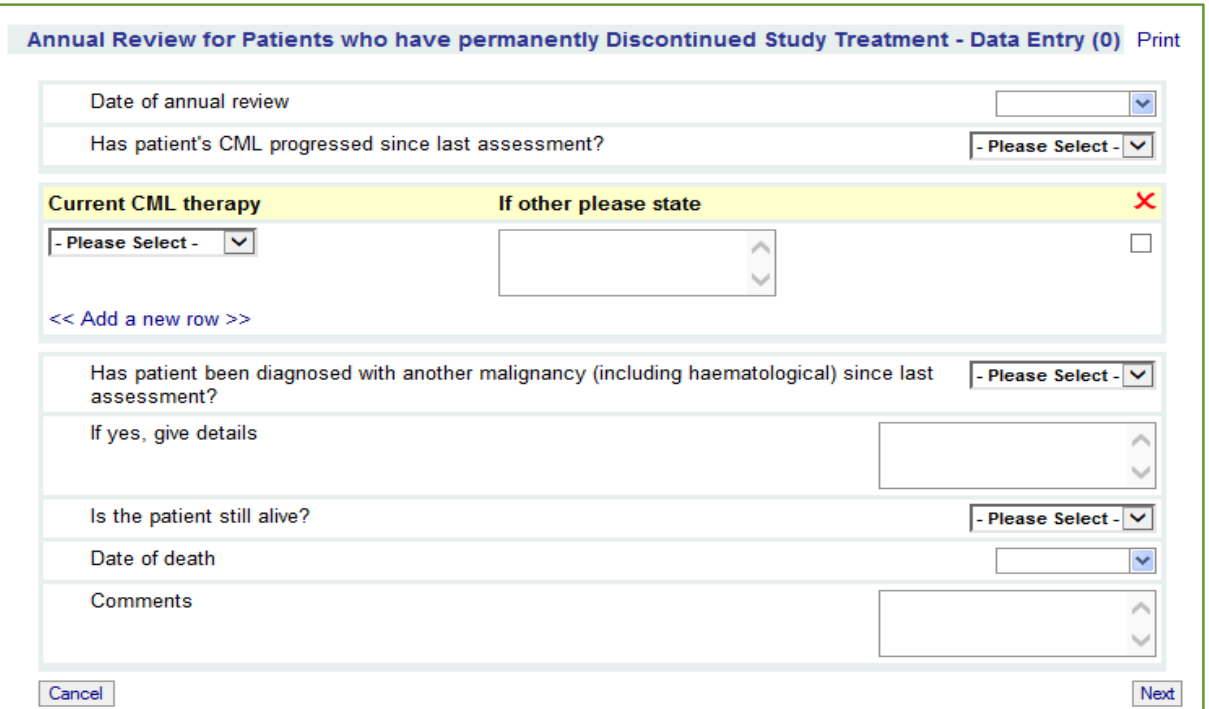
Select the following

Does the patient agree to us continuing to record their PCR results and information about their disease?

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



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