SPIRIT 2

STI571 Prospective International Randomised Trial

DATA NEWSLETTER

September 2016

Issue 1: End of trial and SAEs

Welcome

Welcome to the first SPIRIT 2 data newsletter. As we continue to analyse data collected in the SPIRIT 2 trial, we hope these will provide guidance on data entry.

As patients have begun to reach study completion we have provided some guidance on how to report this in the eCRF. With SAEs featuring highly in our analyses, in this issue we will also focus on SAE data entry.

Upon reaching visit 15

Please complete the following pages in addition to updating all adverse event and concurrent medication pages:

1. Visit 15
   - Complete as you would any other visit

2. Patient outcome page
   - Discontinuation reason will be 'study finished'

3. Study drug log
   - Add entry for study drug completion
   - Reason for change being 'study drug permanently discontinued'
   - Discontinuation date will be the visit 15 date

Imatinib patients and Dasatinib patients (not continuing to receive study Dasatinib after visit 15):

- The drug dose should be recorded a '0mg'
- The frequency should be recorded as 'OD'
- If study drug permanently discontinued will the annual follow up visits be completed for the study? Should be recorded as 'No'

Dasatinib patients- continuing to receive study Dasatinib after visit 15:

- The discontinuation date will be the Visit 15 visit date
- The drug dose should be recorded as the dose the patient is currently on
- The frequency should be recorded as 'OD'
- In comments field add a note of 'Patient continuing on follow up supply of Dasatinib'
- When these patients stop receiving Dasatinib another permanent discontinuation should be recorded with an updated stop date and a dose of 0mg

Early study drug discontinuation

Please complete the following pages in addition to updating all adverse event and concurrent medication pages:

1. Patient outcome page
   - Select a reason for discontinuation
   - Only use 'other' after discussion with the study team, if used please provide as much information as possible in comments field

2. Study drug log page
   - Reason for change will be 'Study drug permanently discontinued'
   - The discontinuation date will be the date the study drug was last taken
   - The drug dose should be recorded as '0mg'
   - The frequency should be recorded as 'OD'
   - Please indicate whether or not the annual follow up visits will be completed for the patient

3. Annual review pages
   - To be completed annually on the anniversary of the patient's randomisation until the patient reaches 5 years from randomisation
   - Annual visits will coincide with when patients would have been due for visit 7, 9, 11, 13 and 15
   - Please provide as much information as possible on these pages

Supplementary guides

Supplementary 'how to guides' for discontinuation and visit 15 eCRF data entry are also available on the SPIRIT 2 website:

www.spirit-cml.org

Data prep

- One month prior to monitoring visits sites will receive a 'data prep' document with inconsistent and outstanding data items
- We hope this will facilitate any data entry prior to our monitoring visit
- If you need any assistance with these queries please contact your Trial Manager or the Database Officer who sent the document to you

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Spotlight on SAEs

The SPIRIT 2 protocol requires the following to be reported as SAEs:

- Any event that results in death
- Any event that requires hospitalisation:
  - Overnight stay as an inpatient
  - Includes elective admissions that are unrelated to the patient's CML or treatment
- Any event that prolongs an existing hospital stay
- Any event that results in persistent or significant disability/incapacity
- Any event that is life threatening
- A congenital anomaly/birth defect in the newborn of a patient or patient's partner
- Any other event that is considered a significant medical event
- Progression of the patient's CML to accelerated phase or blast crisis
- Any cancers diagnosed whilst the patient is on trial treatment (added to protocol version 2.0 which will be rolled out in the near future)

Reporting an SAE

- The SPIRIT 2 SAE reporting form can be found on the SPIRIT 2 website
- SAE forms should be faxed to the Trial Office on:
  0191 376 0748
- If you do not have access to a fax machine reports can be scanned and securely emailed (nhs.net to nhs.net) to:
  tnu-tr.spirittrials@nhs.net
- Follow up information should be added to the original SAE form. Any additions or amendments should be clearly initialled and dated.
- Follow up forms MUST to be faxed or emailed to the Trial Office

Key Points

- SAEs MUST be reported within **24 hours** of the site becoming aware of the event
- It is useful to record the date you were made aware of the event when reporting a SAE (this helps us confirm if the report was submitted within the reporting timeframe)
- In order to meet the reporting timeline you can submit an initial report with limited information however you must include at minimum:
  - Patient ID
  - Event title
  - IMP details
  - Expedited reporting (seriousness) criteria
- The following critical information should be provided as soon an possible (ideally on the initial report):
  - Onset date – the first signs and symptoms even if this is not the date it became serious
  - Causality Assessment – must be assessed by the PI or delegated Co-Investigator
  - PI or delegated Co-Investigator signature – we are unable to accept the causality assessment as valid until we have a signature

eCRF data

- All SAEs must be recorded in the eCRF (please ensure on the AE page that 'serious' has been selected)
- Please ensure an AE page has been created as soon as possible after submitting a paper SAE form
- SAE form data **MUST** be identical to data entered into the eCRF – queries will be raised for every discrepancy

SAE reconciliation

As part of our SAE reconciliation process we need to ensure all details in the eCRF record of the event match the details on the SAE form (same title, onset and resolution dates, causality etc.)

If you update the SAE form please ensure you also update the eCRF record of the event (and vice versa)

CML professional and patient day

- 23rd and 24th September 2016 at the Midland hotel, Manchester
- Spaces are still available for both days

Contact us

As always if you have any questions regarding any aspect of the SPIRIT 2 trial please don't hesitate to call or email the Trial Office:

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