SPIRIT 2
STI571 Prospective International Randomised Trial

DATA NEWSLETTER

January 2017

Issue 2: Updates

2017 onwards…

We have several upcoming changes to SPIRIT 2, further in-depth details will be sent to you in due course. In summary:

- SAE's
  - Detailed reporting guidelines are now online
- New SPIRIT website
  - Same address just a different look. Have a look at the new FAQ section
- Upgraded eCRF
  - The system will now be compatible with chrome, firefox and safari
  - Training and user guidelines detailing the changes will be distributed
  - Secure documents section

Amendment

- We have circulated details of our recent protocol amendment to all sites.
- Any patients who are still taking study medication, which is all patients on imatinib or dasatinib who have not reached visit 15 and all patients on post 5 year supply of dasatinib will need to re-consent.
- We would appreciate it if sites could continue to send the local R&D approvals/acknowledgements to the trial office along with copies of the signed PI signature page and signed consent forms.
- Please visit the SPIRIT 2 website for more information.

Dasatinib supply

- All patients continuing on dasatinib after visit 15 (5 years) will be provided with free trial drug until March 2018.
- Recent NICE guidance has recommended first and second line dasatinib for routine use in the NHS[1]. We plan to transition from trial stock to NHS stock after March 2018.
- Please remember to complete the study drug log for patients who continue on dasatinib after 5 years.

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:

T: 0191 282 0904
E: wendy.banks@ncl.ac.uk

Causality Assessment for AEs and SAEs- Briefing for PIs and Co-Investigators

All AEs should be assessed for causality (whether or not related to the trial drug)

- This assessment MUST be performed by the Principal Investigator or a delegated Co-Investigator (they must be on the delegation log with this role at the time of reporting)
- Causality assessment should be clearly documented in the source data (patient notes)

A PI or Co-Investigator is required to sign-off all SAE forms (either page 2 or page 3) to confirm the causality

- The assessment is documented in section 14 (on page 1) of the form
- The SAE form provides options of 'Suspected' or 'Not Suspected'
- If causality is not clear, assessors are encouraged to take a conservative approach (i.e. report as suspected), however it is acceptable for the investigator to write 'unknown' on the report next to the causality assessment section
- Where 'unknown' is indicated 'suspected causality' will be used in onward assessment of the event
- If the causality assessment of an SAE changes, the investigator must countersign and re-date the SAE form (ideally next to the changed causality) to confirm this
- A reason for a change in causality should also be provided on the narrative section on the form
- If the event title/diagnosis changes the PI or Co-Investigator will need to counter-sign the form (next to the causality assessment) to confirm that the causality assessment is still valid (or they will need to change the assessment if necessary)

The detailed SAE reporting guidelines (available on the SPIRIT 2 website) provide further information on SAE form completion and reporting.

Prompt data entry

We are now preparing data for final analyses and to aid this, we would really appreciate it if you could complete data entry in a timely manner.

To begin with we will be focussing on the following pages:

- Adverse Events
- Visit Date Pages
- Bone marrow
- Demography
- Patient Outcome
- Annual review
- Study Drug Log
- Lab results -Haematology

[1] https://www.nice.org.uk/guidance/ta426/chapter/1-Recommendations