SPIRIT 2
STI571 Prospective International Randomised Trial

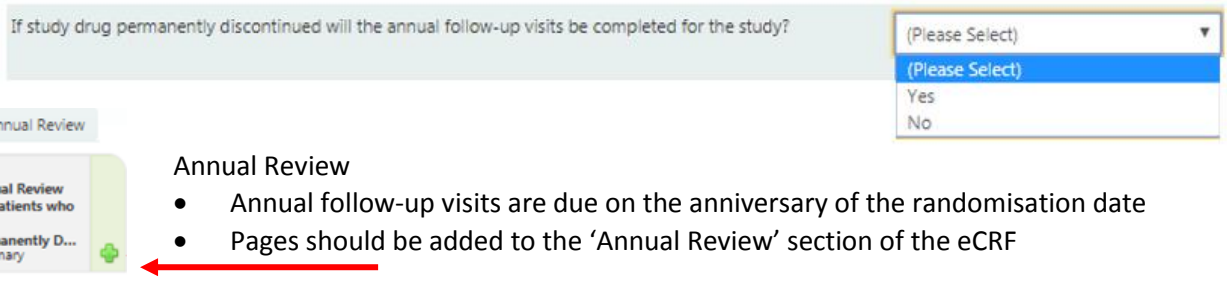
DATA NEWSLETTER
August 2017
Issue 3: Final analysis data

Final Analysis data cleaning

For the remaining months of the study we are focussing our efforts on cleaning data for final analysis. We would like to ensure that data has been entered for the following pages as they are essential in determining whether the patient had an event which contributes to the primary endpoint of the study:

- **Laboratory page – Haematology**
  It is essential that you record all haematology laboratory results that occur during the trial as these are key to helping us assess whether an event has occurred
  - Within the visit book on the eCRF more than one laboratory result page can be created
  - Additional results:
    - Are only to be entered if a patient has had a haematological toxicity or a dose reduction
    - Should be added to the visit it occurs after, i.e. If visit 7 occurs on 10Oct13 and visit 8 is scheduled for 10Apr14, bloods taken on the 3Feb14 should be added to visit 7
  - Where a patient discontinues the study drug but they are happy to be followed up, please add any laboratory results until the patient reaches 5 years from randomisation where possible
  - To add additional laboratory results taken on different dates click the green cross on the 'Laboratory Results' tile within the relevant visit to create a new data entry page

- **CML – Specific Physical Examination**
  - Complete this page even if the procedure has not been performed
  - If not performed document in the comments box at the bottom of the page and submit the page
- **Bone Marrow Analysis – Cytogenetics**
  - Complete this page even if the test has not been performed
  - If not performed document in the comments box at the bottom of the page and submit the page
  - If a bone marrow cytogenetics test was carried out at a non-protocol defined time point and the results were significant then please email or fax the results to the trial office so that the results can be reviewed, particularly if this led to the patient being withdrawn from the trial early
- **End of study pages**
  At the end of the study whether this is at visit 15 or for early discontinuation the following pages must be completed:
  - Study Drug Log
    - Create a new page for when the patient stopped taking the study drug
    - Reason for change will be 'Study drug permanently discontinued' and the dose will be 0mg
      - If a patient has completed the trial and is continuing on Dasatinib enter the dose the patient is continuing on and enter into the comments box 'continuing on trial supply'
      - If the patient discontinues the trial early please pay particular attention to:



Annual Review
- Annual follow-up visits are due on the anniversary of the randomisation date
- Pages should be added to the 'Annual Review' section of the eCRF

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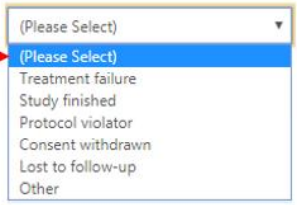
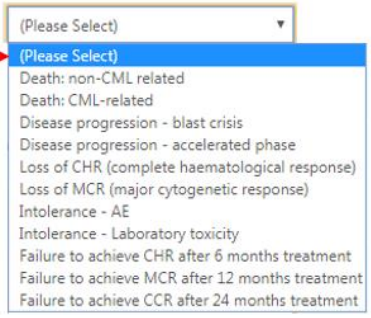
- Visit 15
  - Should only be completed if the patient has completed 5 years on study drug
  - If a patient discontinued early please do not complete any visits after this date
- Patient Outcome
  - Please ensure you are selecting the correct reasons for discontinuation
  - There are a number of sub-options available if the reason for discontinuation is 'Treatment Failure'. These options are listed separately in the next data entry field so please ensure you select 'Treatment Failure' if one of these reasons applies.
  - If more than one Treatment Failure reason applies please select the highest ranking option

Why did the patient permanently discontinue treatment?



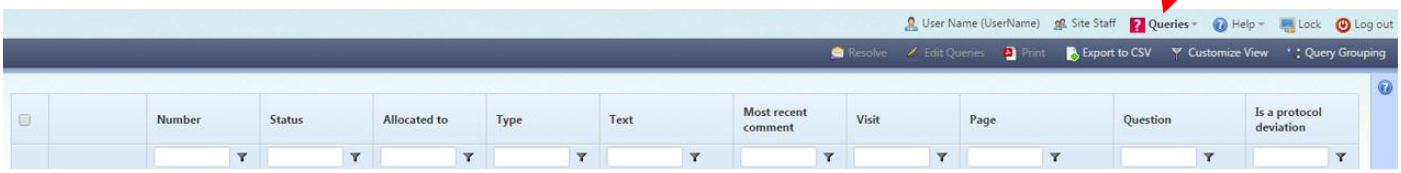
Reason for Treatment Failure:



Queries

In the coming months as we move forward with cleaning the data, you may notice that more queries are being raised on the eCRF. We may also be contacting you by email for clarification on aspects of data that contributes to the analysis.

To access a list of queries for your site navigate to the query module from the menu in the top right hand side of the screen.



Prompt data entry and query review

There are only seven months until Last Patient Last Visit, therefore we ask that you enter data and respond to queries in a timely manner.

To aid you eCRF completion guidelines can be found in the Study Documentation section of the eCRF.

SPIRIT 2 Data Team

Leanne Cork
Project Data Analyst

Nichola Waugh
Database Officer

Look out for emails and queries from Leanne and Nichola over the coming months, we really appreciate your help preparing the data for analysis.

Contact Information

If you have any questions please don't hesitate to contact the Spirit office:

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