

Thank You

2015 was another successful year for the SPIRIT Trials.

This could not have been achieved without the hard work of participating sites and your continued contribution to the study is much appreciated.

SPIRIT Team is growing

We are delighted to welcome a new member of staff to the SPIRIT trial team. Nichola Waugh is our new Data Officer for the study and has joined us from the Newcastle upon Tyne Hospitals NHS Foundation Trust where she worked as a Data Manager.

You will be hearing from Nichola as she looks to clean the data in the eCRF; this will involve querying data already entered and anything missing we would expect to be entered.

Nichola is based within the Newcastle office and her contact details are available on our website at www.spirit-clm.org

End of Year 3 Data

March 2016 saw the SPIRIT trial reach the third anniversary of the last patient entering the study. We will be using this milestone as a cut off for conference presentations and publications which will happen later in the year.

In preparation for this we would like to ask for all data to be entered in the eCRF in a timely fashion, ideally within 14 days of the study visit. The most important pages we need up to date are annual review, patient outcome and study drug log.

To assist with data entry, Nichola has been compiling Frequently Asked Questions and handy tips which will be on the website shortly.

In the meantime, if you have any questions or concerns about data entry in the eCRF please contact your Trial Manager.

PI Changes and Trust Mergers

We would like to remind sites to please keep us informed of any changes to Principal Investigators and any site changes including merging Trusts and Trust name changes as soon as you are aware of the change.

If the Principal Investigator changes at your site please contact your Trial Manager with the following information:

- Date of handover
- New PI CV and GCP
- Updated Delegation Log
- Protocol Signature Page

If there are any site changes, for example Trust mergers or Trust name changes, please contact your Trial Manager with the following information:

- Trust name
- Implementation date
- Website (if applicable)
- Registered address for the Trust
- Registered hospitals
- R&D Office & contacts (inc. email & telephone number)

Menorrhagia

Menorrhagia (heavy periods) appears to be a possible side effect for women on dasatinib and perhaps other TKIs, and is probably under-reported. Please contact the trial office for further advice if you have a patient suffering from this condition. We would appreciate it if Consultants and Research Nurses could remind their patients to report all adverse events, even those they may feel are not related or relevant to their CML treatment.

CML Patient Day

This year's CML Patient Day will be held in Manchester on Saturday 24th September. Could you please mention the event to all CML patients who you think might be interested in attending? For more information please visit <http://www.mpdmeetings.org>