

Thank You

2013 was a very successful year for the SPIRIT Trials.

Recruitment was completed for SPIRIT 2 and we are now progressing well with the follow up phase of the trial.

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

Patients at 5 years (visit 15)



It seems no time at all since we were recruiting the first patients for SPIRIT 2, but it really has been five years since recruitment started and patients are starting to reach the end of study.

We have attached a schematic to this newsletter to help summarise outlined below what happens next depending on the particular scenario for your patient. In summary, patients reaching visit 15 have reached the end of study and revert to standard care.

The exception is patients who have remained on 100mg dasatinib. These patients are assured continued free of charge supply of dasatinib through the trial until the last patient reaches visit 15 (i.e. March 2018). For these patients who continue to receive IMP dasatinib, there is a continued need to record AEs (including reporting SAEs) and keeping the eCRF study drug log updated.

We are extremely grateful to all patients who have participated in SPIRIT 2 and would appreciate it if you could pass on our thanks as they reach the Visit 15 time point.

Dasatinib and Site Closure

Sites who did not recruit patients to SPIRIT 2 or who do not have patients remaining on dasatinib, may still be holding a supply of dasatinib which, following completion of recruitment, is no longer required.

In such cases, any expired stock can be destroyed immediately ensuring that details are added to the destruction log in the pharmacy file. A copy of the destruction log can be downloaded from the study website here or by visiting www.spirit-cml.org documents and downloads section.

If you are holding in-date stock which you do not require and cannot be transferred to another site in your Trust where it can be used, this can be destroyed as outlined above.

If you wish to discuss these arrangements further or have any concerns relating to dasatinib stock, please contact Wendy Banks, wendy.banks@ncl.ac.uk.

We are currently finalising close-down procedures for sites who did not recruit to SPIRIT 2. Please continue to retain your study files and documentation and we will be in contact in due course with arrangements for site close-down.

CML Patient Meeting



Professor Steve O'Brien gave a presentation on the series of SPIRIT Trials at the 2013 CML Patient and Family Meeting on 16 November 2013. Over 90 patients and family members attended the event organised and hosted by

Dr Adam Mead and his team, which was held at Wolfson College, University of Oxford.

Presentations included the history of CML, treatment options and issues, pregnancy and fertility and patient and carer experiences.

Slides from the day are available via the event website, <http://www.mpdmeetings.org/cml-patient-conference-oxford.aspx>

eCRF Con Med Entries

When entering details of concomitant medications to the eCRF you are asked to confirm the reason for use. This includes a concurrent condition or adverse event.

Please use 'adverse event' for treatment for any conditions that have started or worsened since trial entry. 'Concurrent condition' applies where medication is used to treat conditions existing at trial entry.

Where medication is used to treat an adverse event, the event should be recorded in the AE log. Where it is used to treat a concurrent condition, the condition should be recorded in the medical history pages in the eCRF.

Don't hesitate to contact your trial manager if you require clarification or would like to review your entries with them.

SPIRIT 2 slides from ASH

An update on the SPIRIT 2 trial was given at the 2013 American Society of Haematology (ASH) Annual Meeting which took place in New Orleans on 07-10 December 2013.

Slides from the presentation are now available on the SPIRIT 2 Trial website or [here](#).

New members of staff



We are delighted to welcome three new members of staff to the SPIRIT trial team.

Chloe Vasseghi (Trial Manager), Angela Fallows and Laura Brown (Assistant Trial Managers) will be based in the Newcastle office.

Their contact details are available on our website at www.spirit-cml.org.

They are all looking forward to working with you as SPIRIT 2 progresses.



New members of the SPIRIT Trial team. From left to right: Laura Brown, Angela Fallows and Chloe Vasseghi.

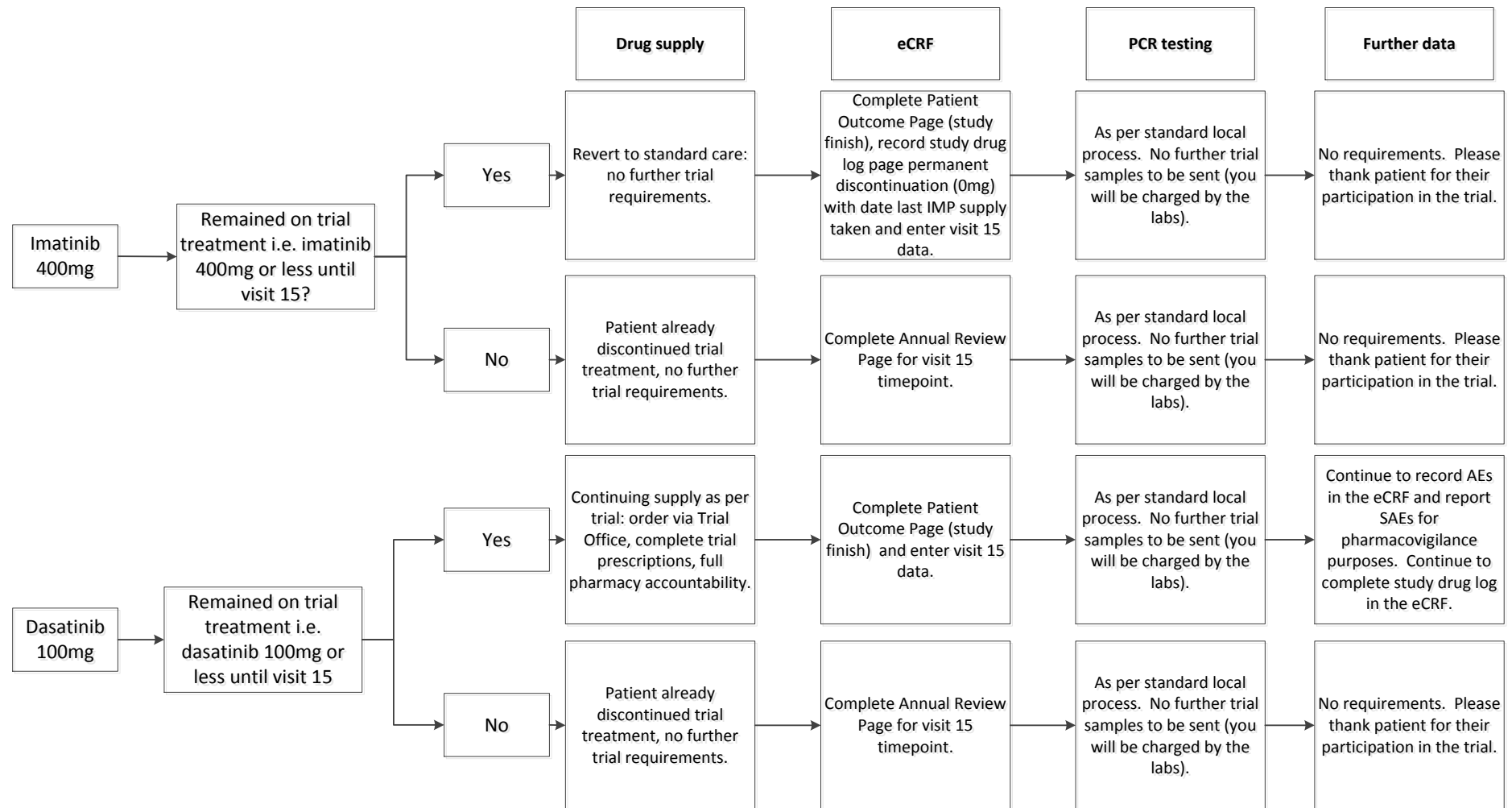
Welcome to Dr Wendy Osborne

It is with great pleasure that we introduce Dr Wendy Osborne who has recently joined the SPIRIT Trials team.

Wendy, Consultant Haematologist at the Freeman Hospital in Newcastle, is providing medical input and advice for SPIRIT 2.

Please continue to contact your Trial Manager should you have clinical queries or concerns and you may be hearing from Wendy in the near future.

SPiRiT 2: End of trial schematic



For all patients: please ensure the eCRF is updated with any missing data, that AEs, study drug log and concurrent medication records are complete and up to date, and that all data queries have been resolved. Your Trial Manager would be very happy to advise – please see <http://www.spirit-cml.org/spirit-2-home/contact.aspx> for contact details.