



## SPIRIT 2 NEWSLETTER

We are delighted to publish this SPIRIT 2 newsletter. It marks a number of milestones in the study. You can find further information about some of these later in the newsletter, but they include : positive recruitment news; a full complement of staff in the Trial Office; the majority of sites now being open for recruitment. Professor Steve O'Brien, Chief Investigator of SPIRIT 2 has commented that

*“the progress with SPIRIT 2 in terms of site set-up, patient recruitment and data completeness is very encouraging. These are all essential components of a successful study and we will use this as a firm base for future years of the trial”.*

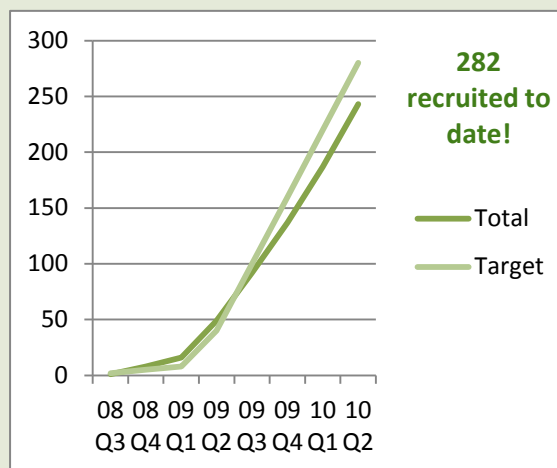
## SAVE THE DATE: CML UPDATE FROM THE SPIRIT 2 TEAM

The SPIRIT 2 team are hosting an online CML Update with the latest news from the Washington CML meeting. This will be on **Friday 15 October from 1-2pm**. The Update is open to anyone working on the SPIRIT studies. We hope that this will enable as many of you to join as possible. More information is available on the SPIRIT 2 website in the news and events section (see <http://www.spirit-cml.org/>). Please see the website for registration and joining instructions.

You can also find information on the website about another meeting on **Friday 17 December** with an update from ASH meeting.

## SPIRIT 2 RECRUITMENT

SPIRIT 2 recruitment has just passed the 280 point. Thank you for getting us more than a third of the way to the total target of 810!



SPIRIT 2: RECRUITMENT TO DATE

We still have work to do however, and recruitment is slightly behind target. We encourage you to remember SPIRIT 2 as a choice for potential patients. If there are any questions about eligibility, or how to randomise a patient, please don't hesitate to contact us. We are always happy to hear from you. Our contact details are listed at the bottom of this page.

A big congratulations to Liverpool, as our top recruiting site for SPIRIT 2. We recognise the hard work that goes into recruitment.

Site	Recruitment
Liverpool	22
Newcastle	11
Nottingham	11
Kent & Canterbury	10
Hillingdon	9

SPIRIT 2: TOP RECRUITING SITES

## FOCUS ON: DATA COMPLETENESS

**We will use this section of the newsletter to focus on a particular aspect of SPIRIT 2. Let us know what you would like to hear about!**

It is essential that SPIRIT 2 has as complete a data set as possible. We need YOU for this!

As many of the secondary endpoints of SPIRIT 2 relate to the cytogenetic and molecular response of patients, this is obviously a key area that we are concentrating on.

As you will know if you have recently had patients going through a 12 month visit (visit 7) we are very keen to follow up to check that bone marrow and PCR data has been collected as per the study schedule as this is crucial for the success of the study, so please expect us to be in touch when the data is due!

Wherever possible, we are trying to get a G Banding result on every patient's bone marrow results. Regulators and reviewers look at G Banding response rates when comparing studies of varying CML treatment options. We need to ensure that the SPIRIT 2 data can provide these adequate comparisons. This is for baseline bone marrow cytogenetics as well as for the annual follow ups at visits 7, 9, 11, 13 and 15. This will ensure that the most is made of the data, and the time that both you and the SPIRIT 2 patients have committed to the study.

You may recall that we recently sent out a survey asking about the access that your site has to G Banding analysis for SPIRIT 2. We would like to thank everyone who was involved in replying to this. We were pleased to see that the vast majority of sites are able to access G Banding analysis, and we would ask you to continue requesting this for all SPIRIT 2 bone marrow analyses wherever possible. If you are having difficulty accessing G Banding analysis, please do get in with us. We will see if there is any way in which we can help.

### The SPIRIT 2 study in numbers:

Number of sites open:	<b>131</b>
Number of patients recruited:	<b>282</b>
Number of patients reached 12 months (V7):	<b>67</b>
Proportion of visit 7 with data complete in eCRF:	<b>57%</b>

SPIRIT 2 NUMBERS: (TO END AUG 2010)

### Your SPIRIT 2 Trial Office

**Professor Steve O'Brien**

Chief Investigator

**Corinne Hedgley**

Senior Trial Manager

**Lynn Seeley**

Trial Manager (field based)

**Caroline Hodgson**

Assistant Trial Manager

**Claire Oyston**

Assistant Trial Manager

**Wendy Banks**

Trial Secretary

**Meg Buckley**

Trial Secretary

SPIRIT 2 TRIAL OFFICE