

500 patient milestone reached

You may have seen from our website announcement that the 500th patient entered the SPIRIT 2 study in early September. This is great news and as ever we are grateful to everyone at sites who has taken the time to offer the study to patients, and to the patients for agreeing to participate. We are getting ever-closer to our recruitment target of 810 patients which is great news for the success of the study.

SPIRIT 2: Benefit beyond patients

The potential benefits to future CML patients from the outcome of SPIRIT 2 are obvious; however the study is also helping to make improvements at our centres. A new Research Nurse post has been created at a SPIRIT 2 site due to the impact of the study. We estimate that SPIRIT 2 will save the NHS up to £40 million in total. 50% of patients on the trial receive free drug for at least 5 years saving the equivalent cost of the NHS providing imatinib. These savings enabled the creation of the research nurse post. This is really positive news, and we hope this might be something other sites can emulate. We would be interested to hear of any other examples of the benefits of having the SPIRIT 2 study at your site. Please get in touch with us and let us know your stories!

Welcome to Kerry Oliver

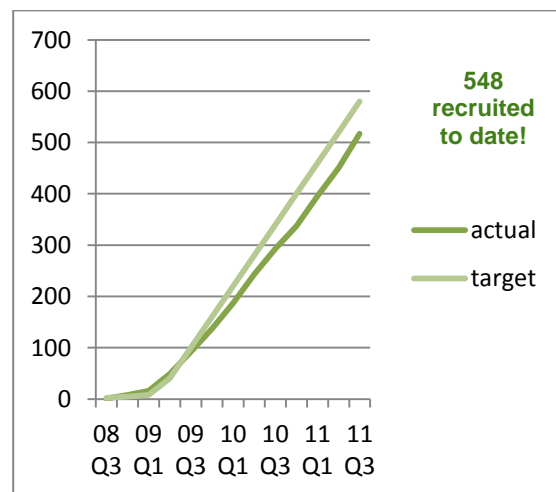


We are delighted that Kerry Oliver has recently joined the team as Assistant Trial Manager. Kerry has replaced Claire Oyston who has moved to another position in the

Newcastle Clinical Trials Unit. Kerry has been in touch with those sites where she will be the primary Trial Manager and is looking forward to supporting you with the SPIRIT trials.

Post-treatment follow up

Patients discontinuing study medication, are still considered 'On Trial' and should continue to be followed-up and the eCRF completed (apart from those withdrawing consent). This is of particular importance as SPIRIT 2 is a long term study with survival at five years as the primary endpoint. If you have a patient in this situation please let us know and we can clarify the logistics in terms of follow up and data collection.



SPIRIT 2: RECRUITMENT TO DATE

Monitoring visit findings

We are really enjoying our monitoring visits, and the opportunity to get out to sites and meet those of you supporting the SPIRIT 2 study. There have been some common findings at recent visits. If you have not been monitored recently, it may well be worth checking that these are in place locally.

- Please ensure that the two substantial amendments relating to the dasatinib label changes have been notified to your R&D departments. This should be filed in section 9 of the ISF. Copies of the ethics and MHRA approvals should be filed in sections 11 and 12 of the ISF respectively. The amendment documentation can be found on our website in the documents and downloads area (see under both

- MHRA and ethics sections). This relates to amendments that were processed in August 2009 and January 2010.
- Please ensure that you are using version 2 of the screening log (available in the documents and downloads area of the website under study documentation).

Please don't hesitate to get in touch with us if you have any questions about these actions.

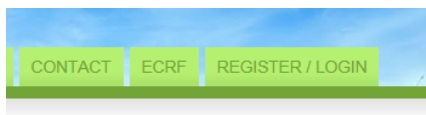
Website – secure access

A number of upgrades have been made to the technical side of the SPIRIT 2 website. We are now able to mark documents as 'secure' and only available to people registered as users of the website. This will enable us to share documents that are commercially sensitive and could not be placed on the website whilst it was openly accessible. This includes items such as Investigator Brochures, eCRF completion guidelines etc. We aim to leave as much material as possible freely available, but hope that having this facility will make access to the whole range of study documentation much easier for you.

To be able to access these documents you will need to register for the website, and will have to be logged in. You can opt to have the website remember your details.

To register:



- Go to the website:
<http://www.spirit-cml.org/>.
- Select SPIRIT 2 website link.
- Select the 'register/login' tab along the top



- Complete your details on the right hand side.
- You will receive an email and will need to verify your email address. Your registration request will also need to be authorised by the Trial Office.
- Once you are set up, you will be able to access all of the documentation. You can tell if you are logged in because the green tab at the top will say 'logout' rather than

give you the option to log in. You can set the system to 'remember you' so you do not need to log in each time if you are using the same computer.

- If you are logged out, any secure documentation will be listed as requiring a log in.

 **eCRF completion guidelines v1.0** - last updated 04 July 2011
 Sorry to access this file you must be [logged in](#) and have permissions.

Christmas arrangements

The Trial Office will not be staffed from Friday 23 December to Monday 2 January inclusive. Any urgent queries (**including medical queries**) can be directed to the Chief Investigator, Professor Steve O'Brien on 07590 527 363. Serious Adverse Events should continue to be reported in the normal way by fax to 0191 376 0748.

Please ensure **drug orders** to last for the Christmas period are placed by **12pm on Monday 19 December**. Please order sufficient to last until 15 January 2012. The early weeks of January are very busy and deliveries can be delayed; this will ensure that you have supplies for this whole period.

Due to the Christmas period **no samples should be posted to the central labs** (PCR at Hammersmith or Biobank at Glasgow) **after Tuesday 20th December or until Monday 9th January inclusive**. Please plan your patients' visit schedules accordingly. If potential new patients present during this time, if it is clinically safe to do so they may be treated with hydroxycarbamide and/or anagrelide until it is possible to take the baseline (pre study drug) samples.

548

patients recruited

Royal Berkshire Hospital

Recruited 500th patient

Meetings for your diaries!

Following the success of last year's meeting, we are arranging a **post-ASH CML update meeting for Friday 16 December at 12.30pm**. This is an online meeting so we hope you will be able to fit this into your busy diaries. Details will be on our website as they become available. You can pre-register [here](#) to ensure you receive the information you need (or see the news item on our website).

The annual CML Professionals' meeting will be held on 3 February 2012 in Newcastle. Details will be available soon on our website, but don't forget to add the date to your 2012 diaries when they arrive!

SPIRIT 2 FAQs

Don't miss the new FAQ section on our website (under documents and downloads section on www.spirit-cml.org). We will be expanding this section over time so check back regularly for any updates. Please let us know if there is anything you think we can add here. This could be information about something you are not sure about (don't hesitate to ask!), or a piece of information that you are always having to look up but can't find easily (let us add it here so you know where to find it). Also let us know if there is something you have found out that you think would help other sites – we can add it here to help everyone! Just get in touch with Caroline on c.hodgson@ncl.ac.uk. She'd love to hear from you!

Patient access

You will probably be aware that the SPIRIT 2 PIS includes details about patients accessing their own trial information over the web using a personal username and password. This will allow them to check that personal details about them are correct and to see their own results and progress in the trial. We are pleased to say that we are making good progress with this. We have had a favourable ethical review for our plans to manage this and are currently finalising arrangements for how patients will receive their log on details if they would like them. We will be in touch in the New Year with details of how the system will work. We know that some patients have already been in

touch about this access; please be reassured that we are still committed to delivering this.

Website documentation

The following documents have been added to the SPIRIT 2 website. These can be located from the documents and downloads section at www.spirit-cml.org. *You will need to be logged in to access many of these as described earlier. Please note we are now using document control version 11.

Study documentation section:

- Updated contact list for Trial Office for filing in ISF and pharmacy file. Please file in section 1 of the main ISF and pharmacy file.
- *eCRF completion guidelines (version 1.0).
- *Quality of Life questionnaires (FACT-BRM and EQ5D) and *PCR/Biobank shipping forms have been added for ease of access.

Pharmacy section:

- *Dasatinib Investigator Brochures. These have previously been sent to pharmacies on CD, but are added here for ease of access.

Annual safety reports:

- 2010/2011 reports for MHRA and MREC. Section 6 of the ISF should have a file note to reference the location of these on the website and these do not need to be printed. Please contact the Trial Office if you do not have this.

SUSAR reports:

- *Dasatinib SUSARs 03 and 04 added. Please ensure this is printed and filed in section 6 of your ISF.