



## 370 PATIENTS RECRUITED

We are heading towards the half way point of our total recruitment target of 810 patients.

We had a great response to our recruitment survey, and we are grateful to everyone who took the time to respond. Many sites felt that a trial synopsis would be useful (e.g. for use at MDT meetings) and are preparing one of these for circulation. We are also picking up site-specific points that have been raised and will be in touch directly about these.

Thanks to those sites who have recruited their first patient(s) since the last newsletter:

- Belfast City Hospital (2 patients)
- Darent Valley (2 patients)
- Hairmyres Hospital
- Queen's Hospital, Burton
- Royal Albert Edward Infirmary
- Royal Gwent Hospital
- Royal Hallamshire
- Tameside
- University Hospital of North Staffs
- University Hospital of South Manchester
- Victoria Infirmary, Glasgow

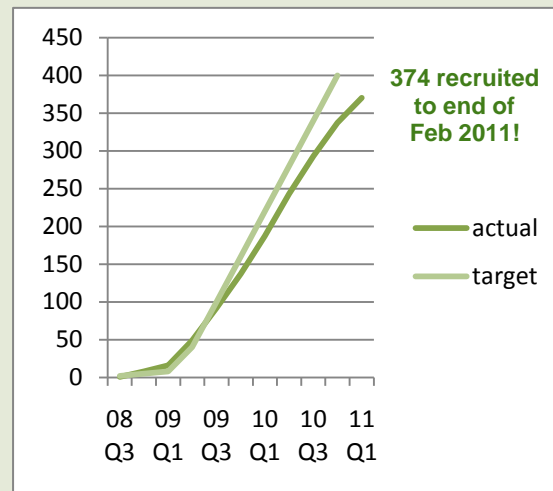
## PCR/BIOBANK SAMPLES AT EASTER

The central labs will be closed over the Easter and Bank Holiday periods affecting samples for Hammersmith (PCR) and Glasgow (Biobank).

The **last posting date for samples will be Monday 18 April** and no more samples should be sent until **Monday 2 May**.

Please could you review your patient study schedules and make any necessary adjustments to ensure that samples are sent accordingly over this two week period?

If potential new patients present during this time, if it is clinically safe they may be treated with hydroxycarbamide and/or anagrelide until it is possible to take the baseline (pre study drug) samples.



SPiRiT 2: RECRUITMENT TO END FEB 2011

## eCRF TRAINING

We are really enjoying getting out to sites to conduct monitoring visits, and meeting everyone who is working so hard on the SPiRiT 2 study. We have had a number of requests for refresher eCRF training, as well as specific training for specific aspects of the system. We will be publishing a series of dates for refresher training and for specific areas such as query resolution. You can check the SPiRiT 2 website for times, and if these do not suit please get in touch as we will be happy to arrange another time that is more convenient for you.

Site	Recruitment
Liverpool	30
Newcastle	14
Kent & Canterbury	13
Nottingham	12
Hillingdon	9
Hammersmith	9

SPiRiT 2: TOP RECRUITING SITES

## FOCUS ON: PHYSICAL EXAMINATIONS

**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!**

During monitoring visits we are noticing that physical examinations are not being performed or documented as per the study protocol. As a reminder, a physical examination is required at each study visit. This should be a general examination and include an assessment of extramedullary disease including liver, lymph nodes and spleen. ECOG score should also be assessed. The physical examination and ECOG score should be documented in the source notes to allow data entry to the eCRF.

Furthermore, we have found occasions where there is no documentation relating to a physical examination, but that data has been entered to the eCRF (e.g. entering 0cm for measurement of liver/spleen below costal margin). Data in the eCRF should be consistent with the source documents (see ICH Guideline for GCP E6 (R1) 4.9.2. The entry of data that cannot be matched back to source documentation is in fact the creation of data that does not exist.

If data has not been documented, any relevant fields in the eCRF should be left blank. Please contact the Trial Office if you are not sure how to do this and we will be happy to show you.

### DATA COLLECTION AIDS

We have worked with some sites to develop templates for use to aid data collection. These can range from prompt sheets to remind you of data required at each visit, to the design of labels to place in the medical notes for completion at visits. We are happy to work with you to design these to fit in with your local practices. Please just get in touch with the Trial Office if this would be helpful.

#### The SPIRIT 2 study in numbers:

Number of patients recruited: **374**

Number of patients reached 12 months (V7): **148**

% Visit 7 cytogenetic data complete in eCRF **62%**

Top recruiting site since last newsletter: **Western General, Edinburgh (Dr Shepherd)**

SPIRIT 2 NUMBERS: (TO END FEB 2011)

#### Your SPIRIT 2 Trial Office

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Chief Investigator

**Corinne Hedgley**

Senior Trial Manager

**Lynn Seeley**

Trial Manager (field based)

**Caroline Hodgson**

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**Meg Buckley**

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