



322 PATIENTS RECRUITED

We are delighted to say that we have passed the 300 figure for recruitment to the SPiRiT 2 trial. Congratulations to Dr Turner at Norfolk and Norwich for recruiting patient number 300! A huge thanks to everyone who has contributed to getting to that figure.

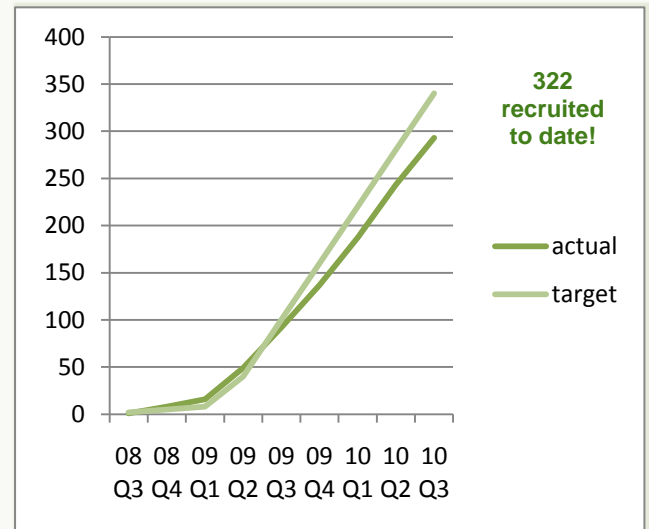
We are very aware of the hard work that goes into recruiting each and every patient. We are currently looking at how we can help you with recruitment and will shortly be circulating an online questionnaire. Keep an eye out for the questionnaire, or get in touch with us to let us know your views.

CHRISTMAS CLOSURE

The **Trial Office** will not be staffed from **Friday 24 December to Monday 3 January inclusive**. Any urgent queries (including medical queries) can be directed to the Chief Investigator, Prof 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 (to 3 January) are placed by **Friday 17 December**.

Due to the Christmas period **no samples should be put into the postal system** to the **central labs** (PCR at Hammersmith or Biobank at Glasgow) from **Friday 17 December until Monday 3 January inclusive**. **Samples posted on Thursday 16 December should be in special delivery boxes only**. Please plan your patient's visit schedules accordingly. If new 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.



SPiRiT 2: RECRUITMENT TO DATE

QUALITY OF LIFE PATIENT LABELS

At monitoring visits we have noticed that quite a few quality of life questionnaires are not labeled with anything to identify which patient and/or visit they relate to. In order to help with this, when a new patient is randomised we will send you a sheet of labels with patient details and visit number for you to use. There will be two labels for each visit (one each for FACT-BRM and EQ5D questionnaires). If you would like labels for patients already randomised, please let Wendy know (contacts below).

Site	Recruitment
Liverpool	27
Newcastle	12
Nottingham	11
Kent & Canterbury	11
Hillingdon	9

SPiRiT 2: TOP RECRUITING SITES

PATIENTS COMING OFF TRIAL

As with many trials, during the course of SPIRIT 2 some patients will need to be moved off protocol treatment to an alternative. We would ask that wherever possible this is discussed with Prof Steve O'Brien (as Chief Investigator) before the patient is removed from the study.

It is helpful for us to know what problems patients are experiencing and we can also discuss with you whether an interruption of study drug might be worth trying before making a final decision on possible alternatives.

If it is decided to take a patient off study drug treatment we would like to continue to follow up these patients for the duration of their original study schedule. Please could you ask your patients if they would be agreeable to this. If so, this should be documented in the medical notes.

If a patient is agreeable please:

- Continue to collect PCR samples to send to central lab (Hammersmith) according to the original study schedule for that patient.
- Complete the patient outcome page in the eCRF
- Complete a study drug log page in the eCRF to record the date they finally stopped study drug.
- Complete the annual review page in the eCRF at the annual visit of the patient's original study schedule (visit 7, 9, 11, 13 and 15).

If patients are not willing to be followed up please:

- Complete the patient outcome page in the eCRF
- Complete a study drug log page in the eCRF to record the date they finally stopped study drug.

VISIT 7 (12 MONTHS) BONE MARROW

Thank you to everyone for continued efforts in ensuring the 12 month bone marrows are completed.

The SPIRIT 2 study in numbers:

Number of patients recruited:	306
Number of patients reached 12 months (V7)	100

Site with most complete bone marrow cytogenetic data entry:
HILLINGDON

SPIRIT 2 NUMBERS: (TO END OCTOBER 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