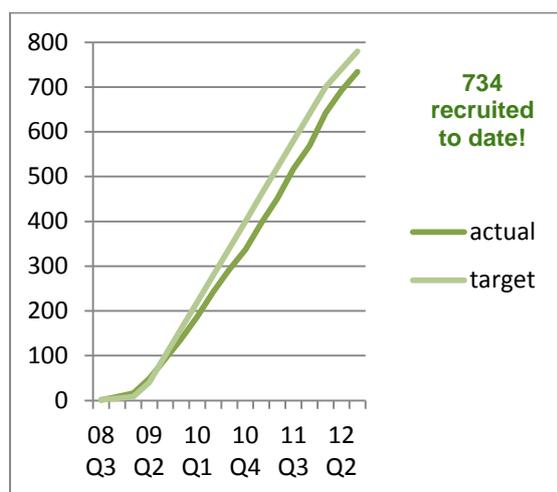


## 700<sup>th</sup> patient recruited

You may have seen from our website announcement that the 700<sup>th</sup> patient was entered into the SPIRIT 2 study and we are now well into the 700's. This is great progress and we appreciate everyone's work ensuring that we reach the full recruitment target of 810.



SPIRIT 2: RECRUITMENT TO DATE

## Office closure day – 14 Sept

The SPIRIT Trials Office will be closed on Friday 14 September for a team training day. If there is an urgent need to contact us (e.g. urgent medical queries) please call 07545 696056.

## Dasatinib tablet strengths

SPIRIT 2 dasatinib supplies are provided in bottles of 20mg and 50mg strengths. We have been notified of two incidents recently where the incorrect strength was dispensed. Neither case resulted in a patient taking an incorrect dose, but we hope that sharing this information will help to reduce the risk of this happening.

The 20mg and 50mg IMP dasatinib bottles are very similar in appearance, and we would be grateful for your help in ensuring that all relevant staff are aware of the differing strengths in use for the study.

Dispensing logs have separate pages for each strength, and you may consider visually separating supplies when stored in pharmacy. This may include clearly identified boxes for each strength, or keeping supplies separated in clear bags or different colour boxes by strength.

## Common Toxicity Criteria – version 2

We have noticed at some recent monitoring visits that sites are using later versions of the CTC. SPIRIT 2 uses CTC version 2, in keeping with the SPIRIT 1 study. For consistency across sites and across the trial, please could you ensure that you are using the correct version. Version 2 is available as an appendix in the back of the protocol.

As an example of the importance of using the correct version, the grading definitions for shortness of breath differ between grade 1 and grade 2 across the different versions:

|         | Version 2           | Version 3  |
|---------|---------------------|--|
| Grade 1 | Not used            | Dyspnea on exertion, but can walk 1 flight of stairs without stopping                              |
| Grade 2 | Dyspnea on exertion | Dyspnea on exertion but unable to walk 1 flight of stairs or 1 city block (0.1km) without stopping |

## Imatinib labels

We have discovered that some pharmacy staff are applying imatinib labels to dasatinib supplies at the time of dispensing. Imatinib supplies for SPIRIT 2 are dispensed from standard NHS stock, but as this is done as part of a ctIMP, clinical trial labelling, as approved by the MHRA needs to be applied. Dasatinib stock is provided direct from Bristol Myers-Squibb with the clinical trial labelling

already applied. Only patient-specific identifiers should be added. Please could you ensure that staff involved in dispensing SPIRIT 2 stock are clear of labelling requirements for the trial, and that any local procedure documentation reflect this.

For clinical trial use only. Keep out of reach of children.  
**SPIRIT 2** EudraCT no.: 2007-006185-15  
 Chief Investigator: Dr S. G. O'Brien.  
 Trial Sponsor: The Newcastle-upon-Tyne Hospitals NHS Trust.

For oral use only. To be used as directed by your doctor.  
 Do not store above 30°C.

Investigator: \_\_\_\_\_ Patient No.: \_\_\_\_\_  
 Site ID: \_\_\_\_\_

Date Dispensed: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

Label for use on SPIRIT 2 imatinib only

## Sample boxes

We are often asked questions about sample boxes. We hope that the following information will answer your more frequent questions, but as ever, please do not hesitate to get in touch if anything is not clear.

### What are sample boxes used for?

Sample boxes are used for sending SPIRIT 2 peripheral blood samples to Hammersmith (for PCR testing) and to Glasgow (at baseline only, if a patient consents to biobanking). The boxes meet the relevant standards required for sending biological samples through the post. In addition, these boxes have the postage pre-paid by the SPIRIT 2 trial.

### What sort of different boxes are there?

Boxes are:

- Marked as either diagnosis or follow up.
- Addressed to Hammersmith (for PCR with 3 sample tubes) or Glasgow (for biobanking with 8 sample tubes).
- Have either first class or special delivery postage applied.



Special delivery (left) and standard first class (right)

### Why different types of postage?

Samples for the SPIRIT 2 study are time-sensitive and should always be posted the same day they are taken. We therefore ask that samples are sent wherever possible on a Monday, Tuesday or Wednesday. However, we realise that the set-up at some sites is such that samples can only ever be sent on a Thursday (e.g. Thursday clinics) and in these instances we provide special delivery postage for which the Royal Mail guarantees next day delivery. We cannot accommodate samples being taken/posted on a Friday. As the costs are covered by SPIRIT 2, pre-paid shipping boxes should only be used for SPIRIT 2.

### How do I post the special delivery boxes?

If you are using the special delivery service, you need to complete the special delivery slip (pictured overleaf) and attach this to the package to assign the relevant tracker number. You should ONLY attach these to sample boxes with the pre-paid special delivery packaging (see above) otherwise the postage will not cover special delivery and they will be sent normal post. You will need to establish what your local arrangements are for postal collection of these packages. They must be identified at pick up by the Royal Mail system as Special Delivery and cannot just be put into the postal system as a normal piece of mail.



You may find it useful to note the tracker number on your local copy of the shipping form in case of problems.

### When are boxes sent out?

When a site is initiated you will be provided with 1 x diagnosis Hammersmith box (PCR) and 1 x diagnosis Glasgow box (biobank) for you to use for new patients. When a patient is randomised we will send replacement diagnosis boxes to you. As we know the visit schedule for each patient on the study, we anticipate when a visit is due and will send you follow up boxes in time for the visit. We send

these on a just-in-time basis to avoid taking up valuable storage space at your site.

### What if I need additional boxes?

Sometimes additional boxes in cases where a patient requires more frequent PCR testing than required by the study protocol. Please let us know when this occurs and we will provide boxes accordingly. There are also occasions when samples need to be repeated because they were not suitable for analysis. In this case we will send you replacement boxes when requesting the repeat sample.

### What is the shipping form for?

This identifies the sample as a SPIRIT 2 sample. This means that it will be flagged for the data to be entered to the SPIRIT 2 eCRF and is the method by which samples are flagged for billing back to SPIRIT 2, so it is important you remember to include this!

### Can we use our own tubes?

Yes, so long as EDTA tubes are used, and they fit in the shipping boxes, you can use your own tubes. If you let us know we will not send tubes to you.

### Should we send bone marrow material?

NO! The SPIRIT 2 protocol does not require bone marrow samples to be sent centrally. Bone marrow results for the study are from local samples analysed as per your routine procedures.

### When are baseline/diagnosis samples taken?

Study specific samples should only be taken once a patient has given written consent (i.e. to the SPIRIT 2 study and/or the biobank study as appropriate). Samples should be taken on the days of the week as described above and prior to study drug being started (this may be after randomisation).

### Other questions?

Don't hesitate to contact us!