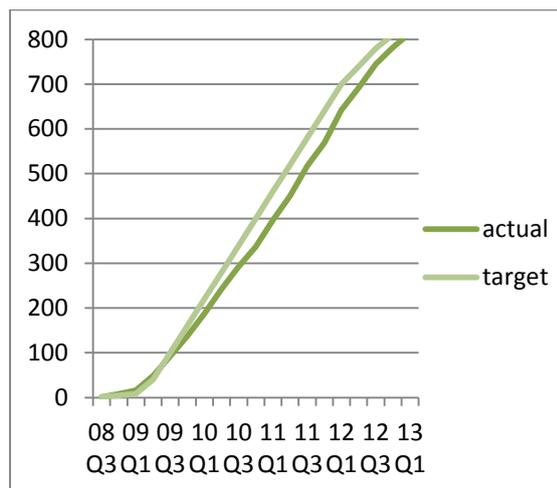


### SPIRIT 2 Recruitment success!

We are delighted to announce that we reached our recruitment target in March 2013. We have carried out a statistical review to ensure that the number of patients recruited will allow us to meet our study endpoints. We are pleased to say this has been confirmed, and SPIRIT 2 is now closed to recruitment having successfully met the recruitment target. 814 patients have been recruited across 145 sites. This is a fantastic collaborative effort and we appreciate everyone's help with this.

The study is now in follow-up, which will continue for the next five years until follow up of the last patient is achieved.



### Office closure day

The Trial Office will be closed for staff training on **Tuesday 30<sup>th</sup> April** – alternative contact arrangements for urgent queries will be provided nearer the time and will be on our website at [www.spirit-cml.org](http://www.spirit-cml.org).



### SPIRIT 2 diagnostic kits

Now that recruitment is closed, no further diagnostic samples will be needed and the shipping boxes can be used as follows:



#### Kits addressed to Glasgow:

No samples should be sent to Glasgow but these can be re-addressed and used for sending follow up samples to Hammersmith for PCR testing.

- Let us know how many boxes you have and we will send new address labels.
- Please remove five tubes from these boxes and discard (as only 3x6mls of blood is required for Hammersmith PCR samples).

**Kits addressed to Hammersmith:** The address indicates the sample is a diagnostic sample – you can simply use these for follow up samples instead.

For any boxes please ensure you include the SPIRIT 2 shipping form (available in the documents and downloads section of our website at [www.spirit-cml.org](http://www.spirit-cml.org)).

### AEs – something to check

Don't forget that if your patients have a marked increase or decrease in weight loss, this counts as an adverse event. The Common Toxicity Criteria (CTC) classification of weight changes can be found under the constitutional symptoms section (see page 49 of the current version of the protocol). Here you will see that weight gain or loss of 5% against the patient's baseline weight is categorised.

It may be that this is intentional weight loss or gain, in which case this should be recorded as 'unsuspected' causality.

## Hospitalisation – SAE reporting

We have found on occasions at recent monitoring visits that SAEs for hospitalisations have not been reported to us. Commonly this is where a patient was admitted to another unit or hospital but was not picked up from the notes at the patient's next trial visit. You may find it useful to review how the trial team is notified of hospitalisation events in patients taking part in clinical trials (e.g. through use of alert stickers). We would also suggest that as part of the routine of asking trial patients about adverse events during their clinic visits, they are asked if they have been admitted to a hospital since they were last seen. This will help pick up any missed events that require reporting as an SAE.

## CML Professionals' Day – slides available to review



This meeting was held on 1 March. There was a great turnout with positive feedback received. You can

view or re-play any of the presentations at your convenience. Just go to the following website, select the meeting and choose to either watch the video or download slides: [www.mpdmeetings.org](http://www.mpdmeetings.org).

Don't forget to add this to your training log too as evidence of your ongoing training and knowledge.

## SPIRIT studies... next step

You may have heard about plans for the next trial, SPIRIT 3. Plans are progressing and we are delighted that funding for this has now been confirmed. We are now finalising the protocol and putting the foundations in place to set this up across the country. Information will be sent out when available, and will be added

to the SPIRIT 3 website which will be available at [www.spirit-cml.org](http://www.spirit-cml.org) once live.

## Contact us!

We are always pleased to hear from you. If

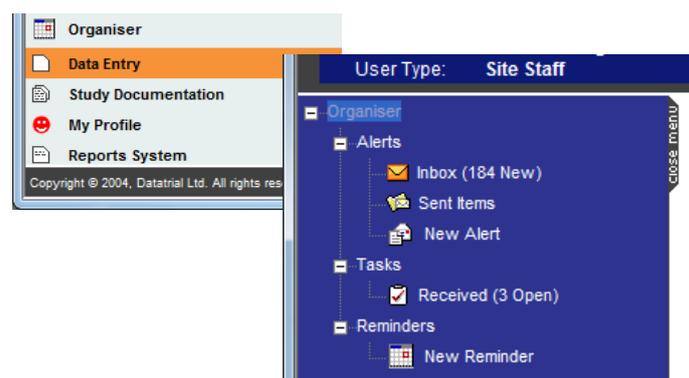


you have suggestions, comments or ever need some guidance please get in touch. Contact details for the whole team can be found on our website at:

<http://www.spirit-cml.org/spirit-2-home/contact.aspx>. Your ISF should also have the current contacts list filed – this can be found in the study documentation area of the website.

## Don't forget to... check for data queries in the eCRF!

There are quite a few unresolved data queries in the system at the moment. It's easy to check to see if you have any. When you are in the eCRF click on organiser in the bottom left hand corner, then from the menu tree choose 'tasks'. Any queries you have will be listed in the 'received' folder (if that is empty, you have no data queries!).



Guidance on how to resolve the data queries can be found in the eCRF completion guidelines available on our website. You can also contact your Trial Manager who would be happy to help with questions or can provide training if needed.