SPIRIT 2
STI571 Prospective International Randomised Trial

Dear Colleagues

SPIRIT 2 – end of trial arrangements for dasatinib patients

Thank you for all the hard work that you have put into the SPIRIT 2 trial – it is greatly appreciated. With 5 years follow up almost complete we are approaching the last patient, last visit milestone on **7th March 2018**. BMS have provided a minimum of 5 years worth of free-of-charge medication for all 407 patients on the dasatinib arm of SPIRIT 2 which has saved the NHS over £40M. As the trial comes to an end in 2018 we have put arrangements in place to ensure that patients taking dasatinib can transition smoothly to NHS-funded commercial supplies.

1. **Transition of all remaining dasatinib IMP patients to commercial stock**

If your site has any patients who are still taking dasatinib trial stock, please ensure that these patients are transitioned to commercial dasatinib before Wednesday 7th March 2018. We have been working with NHS England regarding this transition and a letter has recently been sent to all commissioning leads making them aware that SPIRIT 2 patients will be transitioned to commercial supply. You may already have received this letter locally and a copy is enclosed. You will need to fill out a Blueteq form (England) once for each patient and this will be available from early January 2018.

2. **Remaining dasatinib IMP stock**

No trial prescriptions should be dispensed that go beyond 7th March 2018. For example, the last date that a 3 month trial prescription could be dispensed is Thursday 7th December 2017. Any trial prescriptions dispensed after this date should be for a duration up to, but not beyond, 7th March 2018. **This is in order to comply with MHRA guidance that trial drug packaged as IMP (i.e. not in commercial packaging) must not be used after the trial last patient last visit**. Patients cannot take any leftover stock after this date and must return all tablets to the site pharmacy so they can be accounted for. All patient returns and unused stock must be destroyed in accordance with local guidelines and copies of destruction confirmations sent to the SPIRIT Trials office.

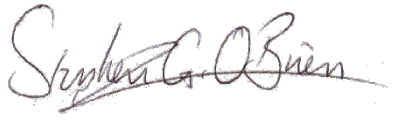
3. **Updating eCRF/safety monitoring**

We would ask that you update the study drug log page of the eCRF for all transitioning patients to reflect the date of the last dose of IMP taken – please use reason “study drug permanently discontinued”, dose “0mg” and add a comment to reflect that the patient transferred to commercial stocks the end of the trial. Please also remember that AEs and SAEs occurring up to 4 weeks after the last dose of IMP must still be reported

Please also read the ‘FAQs’ about this transition and contact the SPIRIT trials office if you have any queries.

Yours sincerely

Stephen OB



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Frequently Asked Questions

Transition of SPIRIT 2 patients on to commercial supplies of dasatinib

Why are you moving patients from trial supplies to commercial supply?	*5 years follow up for all SPIRIT 2 patients will be complete on 7th March 2018. In order to comply with MHRA regulations, IMP can no longer be used after that date. Trial sites will be closed out later in 2018, once all data are collected and analysed.*
Do NHS commissioners know about this?	*Yes. We've worked closely with colleagues at NHS England and Scotland to ensure a smooth transition. First line dasatinib is recommended by NICE for CML (TA426[1]) and therefore funded by the NHS. A letter has been sent to all NHS commissioning groups.*
Dasatinib has been provided free in the trial so far. Who will pay for it after 7th March 2018?	*The NHS has agreed that the drug will be funded as part of routine commissioning as dasatinib is recommended by NICE in this indication. There is a discount provided through the Patient Access Scheme (PAS) detailed in the NICE recommendation.*
What's the latest date that patients on dasatinib have to move from IMP to commercial supply?	*You can start to use commercial supply as soon as you like but no patient should continue on trial dasatinib (IMP) beyond 7th March 2018.*
Do I have to use a Blueteq form for all our dasatinib patients?	*Yes. In England high cost drugs need to be logged using a Blueteq form. You will only have to do this once for each patient.*
I cannot see the Blueteq form on the system yet?	*This should be available from January 2018.*
Do I have to make an individual funding request (IFR)?	*No. NHSE have agreed at a national level to fund the ongoing supply of commercial dasatinib for SPIRIT 2 patients at the end of the trial. No IFRs required.*
I have a patient due a visit in February 2018. how much trial stock can I prescribe?	*Please only prescribe/dispense sufficient stock to last until 7th March 2018. Any remaining IMP stock should then be brought back to the trial site and the patient should be provided with commercial stock to take beyond that date.*
Can I tell the patient to use up any remaining IMP that they have at home after 7th March 2018?	*No. Use of IMP after 7th March 2018 is contrary to MHRA regulations. Patients should bring unused trial medication back to the hospital and be supplied with commercial stock. Sites must be able to show clearly that patients have taken no IMP stock past 7th March 2018.*
What do we do with all stock that we have at site?	*All trial stock remaining at site by 7th March 2018 must be destroyed according to local practice and recorded on the SPIRIT 2 dasatinib destruction log, a copy of which must be sent to the SPIRIT office.*
What about imatinib patients?	*Patients continue on commercial stock as before. Generic imatinib can be used. Imatinib patients should no longer receive trial labelled stock after visit 15 (5 years) on the trial – please do not continue to use trial labels on the stock or record any dispensing on the accountability logs after that date.*

[1] https://www.nice.org.uk/Guidance/TA426