

## SUSAR Summaries

SUSAR reference	SUSAR	Brief Summary
IB V 10 – SUSAR 03	Pneumothorax	<p>Male 60-70 years on dasatinib reported breathlessness at night. Subsequent X-ray confirmed grade 2 pneumothorax and suspected pulmonary emphysema. Treated with thoracentesis.</p> <p>Investigator assessment: Pneumothorax was possibly related to dasatinib treatment.</p> <p>Sponsor Assessment: Pneumothorax was not related to dasatinib treatment.</p>
IB V 10 – SUSAR 04	Squamous cell carcinoma of skin	<p>Male 70-80 years on dasatinib was diagnosed with squamous cell carcinomas of the skin. Patient had a medical history of prior lesions.</p> <p>Investigator assessment: SCCs are possibly related to dasatinib treatment.</p> <p>Sponsor Assessment: SCCs are not related to dasatinib treatment.</p>
IB V 11 – SUSAR 01	Squamous cell carcinoma of skin	<p>Male 60-70 years on dasatinib diagnosed with grade 3 secondary malignancy squamous cell carcinoma of an upper limb. Patient had a prior medical history of skin lesions.</p> <p>Investigator assessment: SCC possibly related to dasatinib treatment.</p> <p>Sponsor Assessment: SCC is not related to dasatinib treatment.</p>
IB V 11 – SUSAR 02	Steatosis hepatic	<p>Male 20-30 years on dasatinib diagnosed with steatohepatitis. Patient presented with elevated AST and ALT. Non-reactive Hep B surface antigen and Hep C antibodies were noted from microbiology.</p> <p>Liver biopsy showed micro and macro vesicular steatosis with foci of acute inflammation. Dasatinib was discontinued however no further treatment was required.</p> <p>Investigator assessment: Steatohepatitis was probably y related to dasatinib treatment.</p> <p>Sponsor Assessment: Steatohepatitis is related to dasatinib treatment.</p>
IB V 11 – SUSAR 03	Metastatic squamous cell carcinoma	<p>Male 60-70 years on dasatinib diagnosed with recurrent squamous cell carcinoma. Patient had a prior medical history of skin lesions including SCC.</p> <p>Investigator assessment: Metastatic SCC related to dasatinib treatment.</p> <p>Sponsor Assessment: Metastatic SCC is not related to dasatinib treatment.</p>

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IB V 11 – SUSAR 04	Maculopathy	Male patient aged 70-80 years on dasatinib. Reported decreased vision and was subsequently diagnosed with maculopathy.
IB V 11 – SUSAR 04 Follow up 01	Maculopathy	Investigator assessment: Maculopathy was related to dasatinib treatment.
IB V 11 – SUSAR 04 Follow up 02	Maculopathy	Sponsor Assessment: Maculopathy was not related to dasatinib treatment.
IB V13 - SUSAR 01	Delirium	Paediatric patient aged 4-10 years on dasatinib. Hospitalised with altered mental status and symptoms of delirium. Investigator assessment: Delirium was related to dasatinib treatment. Sponsor Assessment: Delirium was possibly related to dasatinib treatment.
SPIRIT 2 SUSAR GB-MHRA-ESUSAR- 171360233001- 00097772	Psychotic Episode 21 Apr 2012	SPIRIT 2 female patient aged 70-80 years on imatinib treatment. Hospitalised with confusion subsequently diagnosed as a psychotic episode. Investigator assessment: Psychotic episode was related to imatinib treatment. Sponsor Assessment: Psychotic episode was possibly related to imatinib treatment.
SPIRIT 2 SUSAR GB-MHRA-ESUSAR- 171360233001- 00098345	Nephrotic Syndrome 22 Oct 2013	SPIRIT 2 male patient aged 20-30 years on dasatinib treatment. Presented with mild pitting oedema in the lower limbs and subsequently found to have nephrotic range proteinuria. A diagnosis of Nephrotic Syndrome was made. Investigator assessment: Nephrotic Syndrome was related to dasatinib treatment. Sponsor Assessment: Nephrotic Syndrome was possibly related to dasatinib treatment.
SPIRIT 2 SUSAR GB-MHRA-ESUSAR- 171360233001- 00098439	Hyperthyroidism 04 Sept 2014	SPIRIT 2 male patient aged 60-70 years on dasatinib treatment. The patient was diagnosed with primary hyperthyroidism which, in the opinion of the endocrine consultant was related to dasatinib treatment. Investigator assessment: Hyperthyroidism was related to dasatinib treatment. Sponsor Assessment: Hyperthyroidism was possibly related to dasatinib treatment.
SPIRIT 2 SUSAR GB-MHRA-ESUSAR- 171360233001- 00098419	Failure of bones to unite following left mid- clavicle fracture 30 Mar 2014	SPIRIT 2 male patient aged 30-40 years on imatinib treatment. It was reported that a fracture to the left clavicle, sustained 6 months previously, had failed to heal despite conservative treatment and bone stimulator treatment. Investigator assessment: Failure of the fracture to unite was related to imatinib treatment. Sponsor Assessment: Failure of the fracture to unite was possibly related to imatinib treatment.

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<p>SPIRIT 2 SUSAR GB-MHRA-ESUSAR- 171360233001- 00099870</p>	<p>Myelodysplastic Syndrome 07 May 2016</p>	<p>SPIRIT 2 male patient aged 60-70 years on imatinib treatment. Patient was diagnosed with Myelodysplastic Syndrome. Investigator assessment: Myelodysplastic syndrome was possibly related to imatinib treatment. Sponsor Assessment: Myelodysplastic syndrome was possibly related to imatinib treatment.</p>
<p>SPIRIT 2 SUSAR GB-MHRA-ESUSAR- 171360233001- 00099931</p>	<p>Congenital Anomaly 20 May 2016</p>	<p>The partner of a male SPIRIT 2 patient on dasatinib gave birth to a baby with mild talipes. No other issues were reported. Investigator assessment: Congenital anomaly (talipes) was possibly related to dasatinib treatment. Sponsor Assessment: Congenital anomaly (talipes) was possibly related to dasatinib treatment.</p>
<p>SPIRIT 2 SUSAR GB-MHRA-ESUSAR- 171360233001- 00099928</p>	<p>Atrioventricular Block 20 May 2016</p>	<p>SPIRIT 2 female patient aged 70-80 years on dasatinib treatment. Patient was diagnosed with AV block which was subsequently treated via pacemaker. Dasatinib treatment was also discontinued. Investigator assessment: AV block was possibly related to dasatinib treatment. Sponsor Assessment: AV block was possibly related to dasatinib treatment.</p>
<p>SPIRIT 2 SUSAR GB-MHRA-ESUSAR- 171360233001- 00101285</p>	<p>Moderately to Poorly Differentiated Squamous Cell Carcinoma of Skin 18 October 2017</p>	<p>SPIRIT 2 male patient aged 60-70 years on dasatinib treatment. Patient was diagnosed moderately to poorly differentiated squamous cell carcinoma of the skin which was completely excised. Investigator assessment: SCC of skin was possibly related to dasatinib treatment. Sponsor Assessment: SCC of skin is unlikely to be related to dasatinib treatment.</p>

These are brief summaries only. For full summary information on the above SUSARs see the full reports which are available in the SPIRIT 2 eCRF under 'documents'.  
If you are unable to access these documents via the eCRF please contact the Trial Office on 0191 282 0904 or email [spirit.trials@newcastle.ac.uk](mailto:spirit.trials@newcastle.ac.uk).