

## SPIRIT 2 Investigator Site File Checklist – Generic Documents

Section	Section name	Document	In file?
1.0	Site file	S2 ISF Table of Contents v2.0 (13 February 2012)	
		S2 Documentation Version Control v22 (12 Mar 2018)	
		S2 Monitoring Log	
1.1	S2 Trial Office contact details	S2 Trial Office Contact (10 November 2017)	
		S2 Site Contact details (29 September 2010)	
1.2	Correspondence/Newsletters	Newsletter 11 March 2018	
		End of Trial Dasatinib arrangements letter (05 Dec 2017)	
		Trial in CML provider letter (Dasatinib transition) (23 Nov 2017)	
		Newsletter SAE 1 November 2017	
		Newsletter Data 3 August 2017	
		Newsletter Data 2 January 2017	
		Newsletter Data 1 September 2016	
		Newsletter Data 1 September 2016 supplementary	
		Newsletter 10 April 2016	
		Newsletter 9 July 2015	
		Newsletter 8 February 2014	
		Newsletter 7 April 2013	
		Newsletter 6 December 2012	
		Newsletter 5 July 2012	
		Newsletter 4 November 2011	
		Newsletter 3 March 2011	
		Newsletter 2 November 2010	
Newsletter 1 September 2010			
		End of Trial Schematic	
1.3	Screening and recruitment record	Screening Log v2.0 (11 March 2011)	
		Screening Log v1.0 (27 November 2008) - superseded	
		Site Patient Log v1.0 (27 November 2008)	
1.4	Study specific documentation (part 1)	Location of Source Documents (Source Data Agreement or File note) v1.0 (16 November 2011)	
		Template PIL & ICF v2.1 (02 November 2016)	
		Template PIL & ICF v2.1 - tracked changes (02 November 2016)	
		Template PIL & ICF v2.0 08 June 2016 - superseded	
		Template PIL & ICF v2.0 - tracked changes (08 June 2016 - superseded)	
		Template PIL & ICF v1.2 12 March 2008 - superseded	
		Template GP Letter v1.0 (07 November 2007)	
		Protocol v2.1 (12 December 2016)	
		Protocol v2.0 (30 October 2015) - superseded	
		Protocol v1.4 (20 March 2008) - superseded	
		Dasatinib Patient Alert Card v1.0 (08 June 2016)	
		Dasatinib Patient Alert Card letter to patients v1.0 (08 June 2016)	
		Site specific lab ranges v1.0 (10 February 2009)	
		Pregnancy Reporting Form v1.0 (27 May 2010)	
		Privacy Notice (A4 poster) (14 December 2016)	
Privacy Notice (A5 leaflet) (14 December 2016)			

1.5	Study specific documentation (part 2)	Shipping Form Template v7.0 (14 December 2011)	
		Shipping Form Template v6.0 Hammersmith diagnosis (16 December 2010) - superseded	
		Shipping Form Template v5.0 Hammersmith diagnosis (28 July 2009) - superseded	
		Shipping Form Template v4.0 Hammersmith diagnosis (07 May 2009) - superseded	
		Shipping Form Template v5.0 Hammersmith on study (16 December 2010) - superseded	
		Shipping Form Template v4.0 Hammersmith on study (24 July 2009) - superseded	
		Shipping Form Template v3.0 Hammersmith on study (23 July 2009) - superseded	
		Shipping Form Template v2.0 Hammersmith on study (14 January 2009) - superseded	
		Shipping Form Template v1.0 Hammersmith on study (05 August 2008) - superseded	
		Shipping Form Template v5.0 Glasgow screening (28 July 2009) - superseded	
		Shipping Form Template v4.0 Glasgow screening (27 May 2009) - superseded	
		FACT BRM*	
		EQ5D*	
		1.6	Safety
S2 SAE form v1.0 (20 December 2008) - superseded			
S2 SUSAR Receipt Log v1 (27 January 2012)			
Annual safety reports 2010-2011 (MHRA & REC)			
Annual safety reports 2009-2010 (MHRA & REC)			
Annual safety reports 2008-2009 (MHRA & REC)			
dasatinib DSUR 01*			
dasatinib DSUR 02*			
dasatinib DSUR 03*			
Dasatinib DSUR 04*			
imatinib DSUR 01*			
imatinib DSUR 02*			
imatinib DSUR 03*			
imatinib DSUR 04*			
IBv10 SUSAR 3 Pneumothorax*			
IBv10 SUSAR 4 Squamous cell carcinoma of skin*			
IBv11 SUSAR 1 Squamous cell carcinoma of skin*			
IBv11 SUSAR 2 Steatosis hepatic*			
IBv11 SUSAR 3 Metastatic squamous cell carcinoma*			
IBv11 SUSAR 3 FU1 Metastatic squamous cell carcinoma*			
IBv11 SUSAR 4 Maculopathy*			
IBv11 SUSAR 4 FU1 Maculopathy*			
IBv11 SUSAR 4 FU2 Maculopathy*			
IBv13 SUSAR 1 Delirium*			
S2 SUSAR Psychotic episode*			
S2 SUSAR Nephrotic Syndrome*			
S2 SUSAR Hyperthyroidism*			
S2 SUSAR Fracture non union*			
S2 SUSAR Myelodysplastic syndrome*			
S2 SUSAR Congenital anomaly (talipes)*			
S2 SUSAR Atrioventricular Block*			
S2 SUSAR Squamous Cell Carcinoma of Skin (available by request)			

1.7	Research Personnel	Delegation log v2 (23 November 2010)	
		Delegation log v1 (20 June 2008) - superseded	
1.10	Central Approvals (Sponsorship)	Sponsor Letter (01 October 2008)	
		NHS Indemnity Confirmation (29 November 2007)	
		Chief Investigator CV (07 March 2017)	
		Chief Investigator CV (10 February 2010) - superseded	
		Chief Investigator CV (29 October 2007) - superseded	
1.11	Central Approvals (REC)	<b>Original Application (Protocol v1.2)</b>	
		Letter SPIRIT2 to MREC (07 November 2007)	
		REC Application form (signed 07 November 2007)	
		REC acknowledgement (08 November 2007)	
		REC provisional opinion (03 December 2007)	
		Letter SPIRIT2 to REC (22 January 2008)	
		Letter REC to SPIRIT2 (18 February 2008, reissued 20 September 2010)	
		<b>Amendment - Protocol v1.4 (11-04-2008)</b>	
		Letter SPIRIT2 to REC (14 April 2008)	
		Letter REC to SPIRIT2 (07 May 2008, reissued 08 June 2009)	
		<b>Amendment - IBv8 (19-12-2008)</b>	
		Letter SPIRIT2 to REC (19 December 2008)	
		Letter REC to SPIRIT2 (15 January 2009)	
		Letter SPIRIT2 to REC (22 January 2009)	
		<b>Amendment - Dasatinib label change 1 6154-V-1 &amp; 6155-V-1 (10-08-2009)</b>	
		Letter SPIRIT2 to REC (10 July 2009)	
		Letter REC to SPIRIT2 (25 August 2009)	
		<b>Amendment - Dasatinib label change 2 5733 and 5734 (14-12-2009)</b>	
		Letter SPIRIT2 to REC (02 December 2009)	
		Letter REC to SPIRIT2 (11 January 2010)	
		<b>Amendment - Dasatinib label change 3 50mg vM6999-F-2 (25-06-2012)</b>	
		Letter SPIRIT2 to REC (25 June 2012)	
		Letter REC to SPIRIT2 (24 July 2012)	
		<b>Amendment - Dasatinib label change 4 v7851 (20mg) &amp; v7852 (50mg) (29-05-2013)</b>	
		Letter SPIRIT2 to REC (29 May 2013)	
		Letter REC to SPIRIT2 (05 June 2013)	
		<b>Amendment - Protocol v2.0 (08-06-2016)</b>	
		Letter SPIRIT2 to REC (08 June 2016)	
		Letter REC to SPIRIT2 (04 July 2016)	
		HRA Approval (21 September 2016)	
		<b>Non substantial Amendment (02-11-2016)</b>	
		Letter SPIRIT2 to REC (02 November 2016)	
		Notification of non-substantial amendment form (02 November 2016)	
Letter REC to SPIRIT2 (12 January 2017)			
HRA Reclassification (22 February 2017)			
<b>Substantial Amendment 50 (21-12-2016)</b>			
REC covering letter (14 December 2016)			
Notice of substantial amendment (21 December 2016)			
HRA Categorisation email (06 January 2017)			
REC approval (20 January 2017)			
HRA Approval (03 February 2017)			

1.12	Central Approvals (MHRA)	<b>Original Application (Protocol v1.2)</b>	
		Letter BMS to MHRA dasatinib cross reference (04 December 2007)	
		Letter SPIRIT2 to MHRA (20 February 2008)	
		Letter NUTH to MHRA (12 February 2008)	
		CTA application (07 November 2007)	
		Email EudraCT no. (01 November 2007)	
		Summary NuTH other Imatinib trials	
		MHRA Acknowledgement (17 March 2008)	
		MHRA to SPIRIT 2 non-acceptance (20 March 2008)	
		Letter SPIRIT2 to MHRA response to non-acceptance (11 April 2008)	
		MHRA CTA Acceptance (22 April 2008)	
		CTA Application (11 February 2008)	
		<b>Amendment - Protocol v1.4 (11-04-2008)</b>	
		Letter SPIRIT2 to MHRA (02 May 2008)	
		Annex 1 with highlighted changes	
		Notification of amendment (11 April 2008)	
		Letter response to CTAAC (20 March 2008)	
		MHRA acceptance of amendment (10 June 2008)	
		<b>Amendment - IBv8 (19-12-2008)</b>	
		Letter SPIRIT2 to MHRA (19 December 2008)	
		Notification of amendment (19 December 2008)	
		NUTH Sponsor authorisation of amendment (03 December 2008)	
		MHRA acceptance of amendment (09 January 2009)	
		<b>Amendment - Dasatinib label change 1 6154-V-1 &amp; 6155-V-1 (10-08-2009)</b>	
		Letter SPIRIT2 to MHRA (10 July 2009)	
		Notification of amendment (10 August 2009)	
		MHRA acceptance of amendment (10 September 2009)	
		<b>Amendment - Dasatinib label change 2 5733 and 5734 (14-12-2009)</b>	
		Letter SPIRIT2 to MHRA (02 December 2009)	
		Notification of amendment (14 December 2009)	
		MHRA acceptance of amendment (12 January 2010)	
		<b>Amendment - Dasatinib label change 3 50mg vM6999-F-2 (25-06-2012)</b>	
		Letter SPIRIT2 to REC/MHRA (25 June 2012)	
		Notification of amendment (25 June 2012)	
		MHRA acknowledgement of amendment (06 July 2012)	
		MHRA acceptance of amendment (11 July 2012)	
		<b>Amendment - Dasatinib label change 4 v7851 (20mg) &amp; v7852 (50mg) (29-05-2013)</b>	
		Letter SPIRIT2 to MHRA (29 May 2013)	
		Notification of amendment (29 May 2013)	
		MHRA acceptance of amendment (14 June 2013)	
<b>Amendment: RSI Change (15-03-2016)</b>			
Letter SPIRIT2 to MHRA (04 March 2016)			
Notification of amendment (04 March 2016)			
MHRA acceptance of amendment (26 April 2016)			
<b>Protocol Amendment - v2.0 (08-06-2016)</b>			
Letter SPIRIT2 to MHRA (15 February 2016)			
Notification of amendment (02 November 2016)			
MHRA Acknowledgement (17 February 2016)			

		MHRA acceptance of amendment (21 March 2016)	
		<b>Substantial Amendment 50 (21-12-2016)</b>	
		MHRA covering letter - generic imatinib (14 December 2016)	
		MHRA notice of acceptance of amendment (24 January 2017)	
<b>1.13</b>	Reference Safety Information	Syprcel SmPC section 4.8 (April 2015)	
		Dasatinib IB (November 2007)	
		Glivec SmPC section 4.8 (April 2015)	
		Glivec SmPC section 4.8 (November 2007)	

**Please note**

All documents listed can be found under the corresponding sections in the SPIRIT 2 Website (<http://spirit-cml.org/isf/>) apart from those marked \* or (available by request) - these are secure documents.

Those marked with \* can be found on the eCRF under Study Documentation.

Those marked (by request) can be sent to you directly by the trial team if you do not already have them – please contact [spirit.trials@ncl.ac.uk](mailto:spirit.trials@ncl.ac.uk) with a list of the documents you are missing to receive these.

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