

SPIRIT 2 DOCUMENTS VERSION CONTROL

Current Versions				
Document	Version	Version Date	Effective From	Checked
INVESTIGATOR SITE FILE				
Protocol*	1.4	20 Mar 2008	07 May 2008	
Patient Information Sheet / Informed Consent Form*	1.2	12 Mar 2008	07 May 2008	
GP Letter*	1.0	07 Nov 2007	18 Feb 2008	
EQ 5D Questionnaire*	UK version	Dated 1990	18 Feb 2008	
FACT BCRM Questionnaire*	n/a	Dated 1997	18 Feb 2008	
Lab ranges *	1.0	10 Feb 2009	18 Feb 2008	
SAE Form*	2.0	01 Aug 2009	01 Aug 2009	
Site Delegation Log*	2	23 Nov 2010	02 Dec 2010	
SUSAR Receipt log*	1	27 Jan 2012	13 Feb 2012	
Screening Log*	2	11 Mar 2011	11 Mar 2011	
Site Patient Log*	1	27 Nov 2008	27 Nov 2008	
Clinical Trial Agreement	1.0	22 Jul 2008	22 Jul 2008	
Note, this refers to the versions initially sent to R&D departments for consideration. The fully executed agreement does not have a version number/date as site-specific changes may have been made. Each CTAg will be individually signed and dated.				
Spirit 2 shipping form (combined form for central labs for PCR and Biobank samples)*	7	14 Dec 2011	19 Dec 2011	
Source data agreement	1.0	16 Nov 2011	21 Nov 2011	
PHARMACY FILE				
Pharmacy Manual – Information for Pharmacists*	3.0	27 May 2014	23 Jul 2014	
Study Drug Receipt Log – Dasatinib 20mg and 50mg – Trial Stock*	2.0	12 Nov 2010	02 Dec 2010	
Study Drug Destruction Log – Dasatinib 20mg and 50mg – Trial Stock*	1.0	12 Nov 2010	02 Dec 2010	
Dasatinib Order Form*	3.0	23 Jun 2011	23 Jun 2011	
Dispensing & Return Medication Record*	1	15 Jul 2008	15 Jul 2008	
Spirit 2 Clinical Trial Prescription*	1	15 Jul 2008	15 Jul 2008	
Investigator Brochure Dasatinib*	15	23 Jun 2015	23 Feb 2016	
Imatinib SmPC	n/a	23 Aug 2007	18 Feb 2008	
Note: this is the SmPC version in use at the trial outset. Updates are listed on the eMC website (see filenote in pharmacy file).				

*These documents are available from the SPIRIT 2 website (some documents may require secure log in).

Superseded Versions				
Document	Version	Version Date	Effective From	Superseded
INVESTIGATOR SITE FILE				
Protocol	1.2	21 Jan 2008	18 Feb 2008	07 May 2008
Patient Information Sheet / Informed Consent form	1.1	18 Dec 2007	18 Feb 2008	07 May 2008
SAE Form	1.0	20 Dec 2008	20 Dec 2008	01 Aug 2009
Site Personnel Log	1	20 Jun 2008	20 Jun 2008	02 Dec 2010
Screening log	1	27 Nov 2008	27 Nov 2008	21 Feb 2011
Spirit 2 Biobank Shipping form (Glasgow) – for Biobank samples only at screening	5	28 Jul 2009	28 Jul 2009	19 Dec 2011
Spirit 2 Biobank Shipping form (Glasgow) – for Biobank samples only at screening	4	07 May 2009	07 May 2009	27 Jul 2009
Spirit 2 QPCR Diagnosis Shipping Form (Hammersmith) – for screening samples only	6	16 Dec 2010	04 Jan 2011	19 Dec 2011
Spirit 2 QPCR Diagnosis Shipping Form (Hammersmith) – for screening samples only	5	28 Jul 2009	28 Jul 2009	16 Dec 2010
Spirit 2 QPCR Diagnosis Shipping Form (Hammersmith) – for screening samples only	4	07 May 2009	07 May 2009	27 Jul 2009
Spirit 2 QPCR Shipping Form (Hammersmith) – for on study samples	5	16 Dec 2010	04 Jan 2011	19 Dec 2011
Spirit 2 QPCR Shipping Form (Hammersmith) – for on study samples	4	24 Jul 2009	27 Jul 2009	16 Dec 2010
Spirit 2 QPCR Shipping Form (Hammersmith) – for on study samples	3	23 Jul 2009	23 Jul 2009	27 Jul 2009
Spirit 2 QPCR Shipping Form (Hammersmith) – for on study samples	2	14 Jan 2009	14 Jan 2009	23 Jul 2009
Spirit 2 QPCR Shipping Form (Hammersmith) – for on study samples	1	05 Aug 2008	05 Aug 2008	14 Jan 2009
PHARMACY FILE				
Pharmacy Manual – Information for Pharmacists	2.0	14 Oct 2011	14 Oct 2011	23 Jul 2014
Pharmacy Manual – Information for Pharmacists	1.4	2 Aug 2010	2 Aug 2010	14 Oct 2011
Pharmacy Manual – Information for Pharmacists	1.3	10 Jun 2009	10 Jun 2009	02 Aug 2010
Pharmacy Manual – Information for Pharmacists	1.2	Not published		
Pharmacy Manual – Information for Pharmacists	1.1	27 Nov 2008	27 Nov 2008	10 Jun 2009
Pharmacy Manual – Information for Pharmacists	1.0	10 Jul 2008	10 Jul 2008	27 Nov 2008
Study Drug Receipt Log – Dasatinib 50mg – Trial Stock	1.0	12 Dec 2008	12 Dec 2008	02 Dec 2010
Study Drug Receipt Log –	1.0	12 Dec 2008	12 Dec 2008	02 Dec 2010

*These documents are available from the SPIRIT 2 website (some documents may require secure log in).

Superseded Versions				
Document	Version	Version Date	Effective From	Superseded
Dasatinib 20mg – Trial Stock				
Dasatinib Order Form	2.0	15 Jun 2011	15 Jun 2011	23 Jun 2011
Dasatinib Order Form	1.0	21 Jul 2009	21 Jul 2009	15 Jun 2011
Investigator Brochure Dasatinib	14.0	24 Jun 2014	14 Jan 2015	23 Feb 2016
Investigator Brochure Dasatinib	13.0	19 Jun 2013	21 Feb 2014	14 Jan 2015
Investigator Brochure Dasatinib	12.0	04 Oct 2012	23 Jan 2013	21 Feb 2014
Investigator Brochure Dasatinib	11.0	07 Oct 2011	Not published	
Investigator Brochure Dasatinib	10.0	03 Nov 2010	02 Dec 2010	23 Jan 2013
Investigator Brochure Dasatinib	9.0	03 Nov 2009	03 Nov 2009	02 Dec 2010
Investigator Brochure Dasatinib	8.0	12 Nov 2008	09 Jan 2009	03 Nov 2009
Investigator Brochure Dasatinib	7.0	15 Nov 2007	18 Feb 2008	09 Jan 2009

*These documents are available from the SPIRIT 2 website (some documents may require secure log in).