

SPIRIT 2 Pharmacy Site File Checklist

Section	Section name	Document	In file?
2.0	Pharmacy File	S2 Table of contents v3 (16 Mar 2018)	
		S2 Documents version control v22 (12 Mar 2018)	
2.1	Monitoring	S2 Monitoring log	
		S2 Monitoring reports (Please refer to monitoring log and ensure you have corresponding reports for all monitoring visits)	
2.2	Personnel	S2 Trial Office Contact (10 November 2017)	
		S2 Site Contact details (29 September 2010)	
		Delegation log v2 (23 November 2010)	
		Delegation log v1 (20 June 2008) - superseded	
2.3	Pharmacy Correspondence	Please file all newsletters and relevant pharmacy-specific correspondence here	
2.4	Study Information	Pharmacy manual – Information for Pharmacists v4.0 (13 Sep 2017)	
		Pharmacy manual – Information for Pharmacists v3.0 (27 May 2014) - superseded	
		Pharmacy manual – Information for Pharmacists v2.0 (14 Oct 2011) - superseded	
		Pharmacy manual – Information for Pharmacists v1.4 (02 Aug 2010) - superseded	
		Pharmacy manual – Information for Pharmacists v1.3 (10 Jun 2009) - superseded	
		Pharmacy manual – Information for Pharmacists v1.1 (27 Nov 2008) - superseded	
		Pharmacy manual – Information for Pharmacists v1.0 (10 Jul 2008) - superseded	
		Local dispensing guidelines (as applicable)	
		Protocol v2.1 (12 December 2016)	
		Protocol v2.0 (30 October 2015) - superseded	
		Protocol v1.4 (20 March 2008) - superseded	
2.5	Sample Study drug prescription	SPIRIT 2 Clinical Trial Prescription v1 (15 Jul 2008)	
		If using local prescription, file template copy here	
2.6	Study drug dispensing	Dispensing & Return Medication Record v2 (16 Jan 2017)	
		Dispensing & Return Medication Record v1 (15 Jul 2008) - superseded	
		Completed prescriptions	
2.7	Study drug storage documentation	BMS Temperature excursion response form v0.2 (Dec 2015)	
		Temperature logs (please file local documents in this section)	
		Temperature deviation documentation	
2.8	Manufacturer information	Dasatinib – manufacturers authorisation (13 Jun 2006) <i>(available by request)</i>	
		Dasatinib – QP declaration (04 Apr 2008) <i>(available by request)</i>	
		Dasatinib – license 1595 cover page (08 Jul 2005) <i>(available by request)</i>	
		Dasatinib – TSE documentation (10 Dec 2008) <i>(available by request)</i>	
2.9	Dasatinib labels	Trial specific label - BMS Clinical packaging additional labelling protocol <i>(available by request)</i>	
		Label cross reference file note 20mg (16 Mar 2018)	

		<i>(available by request) (please note, the file note on the eCRF is now out of date)</i>	
		Label cross reference file note 50mg (16 Mar 2018) <i>(available by request) (please note, the file note on the eCRF is now out of date)</i>	
		Sample label 50mg 7852*	
		Sample label 50mg M6999-F-2 – superseded*	
		Sample label 50mg 5734 – superseded*	
		Sample label 50mg 6155-V-1 – superseded*	
		Sample label 50mg N3679-2 – superseded*	
		Sample label 20mg 7851*	
		Sample label 20mg 5733 – superseded*	
		Sample label 20mg 6154-V-1 – superseded*	
		Sample label 20mg N3677-2 – superseded*	
2.10	Imatinib labels	Trial specific label <i>(available by request)</i>	
2.11	Use date extension (UDE) paperwork	Please file UDE paperwork here	
2.12	Reference Safety Information	(Dasatinib) SPRYCEL SmPC (02 Apr 2015)	
		Dasatinib IB v7 (15 Nov 2007) - superseded	
		(Imatinib) GLIVEC SmPC (26 Feb 2015)	
		(Imatinib) GLIVEC SmPC (20 Nov 2007) - superseded	
2.13	Dasatinib receipt log	Study Drug Receipt Log – Dasatinib 20mg and 50mg v2 (12 Nov 2010)	
		Study Drug Receipt Log – Dasatinib 20mg and 50mg v1 (12 Dec 2008) - superseded	
2.14	Dasatinib orders and shipment	Dasatinib Order Form v3 (23 Jun 2011)	
		Dasatinib Order Form v2 (15 Jun 2011) - superseded	
		Dasatinib Order Form v1 (21 Jul 2009) - superseded	
		Completed order forms	
		Confirmation of delivery paperwork	
2.15	Dasatinib destruction (undispensed stock)	Study Drug Destruction Log – Dasatinib 20mg and 50mg v1 (12 Nov 2010)	
		Certificates of destruction (local)	
2.16	Dasatinib supporting documentation	Certificates of analysis	
		Batch release certificates	

Please note

The section numbers above are a guide and only applicable if using the SPIRIT file contents order. If you are using your local file set-up then please use the above as a check.

All version controlled, non-local 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 – the trials team at your site will have a login which can access these.

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 with a list of the documents you are missing to receive these.

Please fax copies of drug destruction logs/documentation to the Trial Office on 0191 376 0748 or email to spirit.trials@ncl.ac.uk