Site Name:

Pharmacy Site File – document version checklist

Complete 'yes' or 'no' to confirm the presence or absence of each document specified. Any missing documents will be provided to you for the Pharmacy SF by UCL CTC following return of this checklist.

Section	Document Name	Current Version	Date	Present?		Comments
01	**TRIAL MANAGEMENT**					
	CTC Contact List	6.0	08feb17	Y ☐	N ☐	
	Site staff delegation log	1.0	08aug11	Y ☐	N ☐	
	Site activation letter	1	1	Y ☐	N ☐	
02	**ETHICS & REGULATORY APPROVALS *** ***sites must have the initial approval letters, site approval letter and all relevant subsequent approvals**					
	Ethics approval letter (Main REC)	-	13jan10	Y ☐	N ☐	
	MHRA approval letter	-	13jan10	Y ☐	N ☐	
	Amendments– MHRA Approval Letters	PIS v2 Protocol v2 Protocol v3 Labelling Protocol v4 Protocol v5 Protocol v6 Protocol v6.1 Protocol v7 Protocol v8 Protocol v9	23feb10 21jun10 17sep10 03nov10 09may12 27sep12 15jul14 11mar15 15nov15 15Jun16 13Mar17	Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐	N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐	
	Urgent Safety Measure Correspondence	USM email - Protocol v4	24apr12	Y ☐	N ☐	*Email correspondence sent from CTC 24.04.12 regarding USM*
	Amendments - MREC Approval Letters	Protocol v2 Protocol v3 Consent period Protocol v4 Protocol v5 PIS 4.1 PIS 5 Protocol v6 Protocol v6.1 PIS 5.2, ICF 1.2 Protocol v7 Protocol v8 Protocol v9	07jun10 08sep10 24aug11 16may12 23aug12 17may13 02apr14 09jul14 23feb15 21may15 30sep15 06Jun16 09Mar17	Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐	N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐	
03	**CURRENT PROTOCOL / STUDY INFORMATION**					
	Current approved protocol	9	17Feb17	Y ☐	N ☐	
	Current versions of summary of products characteristics: - Mabthera - Kepivance - Oncaspar - Atriance	 - - - -	 Jun2016 May2013 Jun2014 Apr2015	 Y ☐ Y ☐ Y ☐ Y ☐	 N ☐ N ☐ N ☐ N ☐	
	Roche Six Monthly SUSAR reports	-	26may-25nov13 26nov13- 25may14	Y ☐ Y ☐ Y ☐	N ☐ N ☐ N ☐	

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Section	Document Name	Current Version	Date	Present?		Comments
			26may-17nov14 18nov14-17may15 18may15-17nov15	Y ☐ Y ☐	N ☐ N ☐	
04	**IMP MANAGEMENT**					
	Drug Supply Guidelines	2.1	25feb14	Y ☐	N ☐	
	Drug Accountability logs: - Phase 1 Oncaspar - Phase 1 Rituximab - Phase 2 Nelarabine - Consolidation Oncaspar - Intensification Oncaspar - Palifermin treatment	 2.0 2.0 2.0 2.0 2.0 2.0	 18may15 18may15 18may15 18may15 18may15 18may15	 Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐	 N ☐ N ☐ N ☐ N ☐ N ☐ N ☐	
	Stock Balance Logs: - Oncaspar - Rituximab - Nelarabine - Palifermin	 1.0 1.0 1.0 1.0	 18may15 18may15 18may15 18may15	 Y ☐ Y ☐ Y ☐ Y ☐	 N ☐ N ☐ N ☐ N ☐	
	Drug order forms: - Oncaspar - Rituximab - Nelarabine - Palifermin	 3 1 1 4	 11Feb13 Jan10 29Nov10 09sep15	 Y ☐ Y ☐ Y ☐ Y ☐	 N ☐ N ☐ N ☐ N ☐	
	Rituximab Certificate of Clinical Trial Supply	1	Jan2010	Y ☐	N ☐	
	UKALL14 memorandum to Investigators and Pharmacists	-	26jan16	Y ☐	N ☐	
	UCL-CTC Pharmacy Notification of Temperature Excursion Form	2.0	25feb14	Y ☐	N ☐	
	UCL-CTC Pharmacy Procedure for Reporting Temperature Excursions	1.0	17sep10	Y ☐	N ☐	
	Temperature Monitoring Log Template	1.0	29nov10	Y ☐	N ☐	
	Destruction Log Template	1.0	29nov10	Y ☐	N ☐	
	IMP Label RA submission form – Oncaspar	-	21oct10	Y ☐	N ☐	
	IMP Label RA submission form – Rituximab	-	21oct10	Y ☐	N ☐	

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	IMP Label RA submission form – Nelarabine	-	21oct10	Y ☐	N ☐	
	IMP Label RA submission form – Palifermin	-	21oct10	Y ☐	N ☐	
05	**CORRESPONDENCE**					
	UKALL14 Monitoring Plan	4.0	18oct16	Y ☐	N ☐	
	UKALL14 central monitoring checklists	-	-	Y ☐	N ☐	*Please file all previous versions of checklists here*

Previous versions of all documents listed above must be superseded. Please initial and date to confirm this action has been performed

Date ☐☐☐☐☐☐ Initials ☐

Please provide the email address of the person to whom updated documents should be sent: ☐

The completed form can be returned to ctc.ukall14@ucl.ac.uk or fax to 0207 679 9861

This is intended to support site's own internal systems for maintaining the PSF; **therefore if the checklist is not returned to UCL CTC we will assume that documents contained within your PSF are up-to-date.**

The following are general reminders regarding maintenance of the Pharmacy Site File:

The folder must be stored in a secure location with appropriate/restricted access.

The documents should be filed as per index.
(CTC index or site's own index is acceptable)

Documents generated locally (e.g. local approvals, IMP labels, prescriptions, correspondence, etc.) must be filed in the applicable sections.

Where documents are held in an alternative location, file notes should be present to indicate this.

Up-to-date CVs must be present for all site staff.
(CVs should be signed & dated and updated regularly according to employing institution policy)

GCP certificates must be present (or details of course attended listed in the CV) for all site staff.
(All staff should have attended a course – frequency of repeat training may be dictated by the employing institution policy, or 2 yearly where the institution has no policy, and more frequently when there have been updates to the legal or regulatory requirements for conduct of clinical trials)