

Site Name:						
Pharmacy Site File – document version checklist						
Complete 'yes' or 'no' to confirm the presence or absence of each document specified. Most documents can be obtained from the CTC website: www.ctc.ucl.ac.uk .						
If a document is missing and is not on the website this will be provided to you for the PSF by UCL CTC following return of this checklist.						
Section	Document Name	Current Version	Date	Present?		Comments
01	TRIAL MANAGEMENT					
	CTC Contact List	7.0	29Aug18	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Site staff delegation log	1.0	08aug11	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Site activation letter	1	-	Y <input type="checkbox"/>	N <input type="checkbox"/>	
02	ETHICS & REGULATORY APPROVALS *					
	<i>*sites must have the initial approval letters, site approval letter and all relevant subsequent approvals</i>					
	Ethics approval letter (Main REC)	-	13jan10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	MHRA approval letter	-	13jan10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Amendments – MHRA Approval Letters	PIS v2	23feb10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v2	21jun10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v3	17sep10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Labelling	03nov10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v4	09may12	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v5	27sep12	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v6	15jul14	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v6.1	11mar15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v7	15nov15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v8	15Jun16	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v9	13Mar17	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v11	21Nov17	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Protocol v12	31Aug18	Y <input type="checkbox"/>	N <input type="checkbox"/>		
	Urgent Safety Measure Correspondence	USM email - Protocol v4	24apr12	Y <input type="checkbox"/>	N <input type="checkbox"/>	<i>Email correspondence sent from CTC 24.04.12 regarding USM</i>
	Rejection of Protocol v10 amendment Correspondence	-	12Jul17	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Amendments - MREC Approval Letters	Protocol v2	07jun10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v3	08sep10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Consent period	24aug11	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v4	16may12	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v5 PIS	23aug12	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		v4.0	17may13	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		PIS 4.1	02apr14	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		PIS 5.0	09jul14	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v6 PIS	23feb15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		v5.1	21may15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v6.1	30sep15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		PIS 5.2 ICF 1.2	06Jun16	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v7	09Mar17	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Protocol v8	05Sep17	Y <input type="checkbox"/>	N <input type="checkbox"/>		
	Protocol v9	30Oct17	Y <input type="checkbox"/>	N <input type="checkbox"/>		
	PIS v8	27Jul18	Y <input type="checkbox"/>	N <input type="checkbox"/>		
	Protocol v11					
	Protocol v12					

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03	CURRENT PROTOCOL / STUDY INFORMATION					
	Current approved protocol	12	26Jun18	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Current versions of summary of products characteristics:					
	- Mabthera	-	26Apr2018	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	- Kevivance	-	May2013	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	- Oncaspar	-	Dec2017	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	- Atriance	-	30Apr2018	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Roche Six Monthly SUSAR reports	-	26may-25nov13	Y <input type="checkbox"/>	N <input type="checkbox"/>	
			26nov13-25may14	Y <input type="checkbox"/>	N <input type="checkbox"/>	
			26may-17nov14	Y <input type="checkbox"/>	N <input type="checkbox"/>	
			18nov14-17may15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
			18may15-17nov15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
04	IMP MANAGEMENT					
	Drug Supply Guidelines	4.0	12Mar18	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Drug Accountability logs:					
	- Phase 1 Oncaspar	2.0	18may15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	- Phase 1 Rituximab	2.0	18may15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	- Phase 2 Nelarabine	2.0	18may15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	- Consolidation Oncaspar	2.0	18may15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	- Intensification Oncaspar	2.0	18may15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	- Palifermin treatment	2.0	18may15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Stock Balance Logs:					
	- Oncaspar	1.0	18may15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	- Rituximab	1.0	18may15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	- Nelarabine	1.0	18may15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	- Palifermin	1.0	18may15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Drug order forms:					
	- Oncaspar	4	27Feb18	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	- Rituximab	1	Jan10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	- Nelarabine	1	29Nov10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	- Palifermin	4	09sep15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Rituximab Certificate of Clinical Trial Supply	1	Jan2010	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	UKALL14 memorandum to Investigators and Pharmacists	-	26jan16	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	UCL-CTC Pharmacy Notification of Temperature Excursion Form	2.0	25feb14	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	UCL-CTC Pharmacy Procedure for Reporting Temperature Excursions	1.0	17sep10	Y <input type="checkbox"/>	N <input type="checkbox"/>	

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	Temperature Monitoring Log Template	1.0	29nov10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Destruction Log Template	1.0	29nov10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	IMP Label RA submission form – Oncaspar	-	21oct10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	IMP Label RA submission form – Rituximab	-	21oct10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	IMP Label RA submission form – Nelarabine	-	21oct10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	IMP Label RA submission form – Palifermin	-	21oct10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
05 CORRESPONDENCE						
	UKALL14 Monitoring Plan	4.0	18Oct16	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	UKALL14 central monitoring checklists	-	-	Y <input type="checkbox"/>	N <input type="checkbox"/>	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		
			<input type="text"/>	<input type="text"/>		
Please provide the email address of the person to whom updated documents should be sent:			<input type="text"/>			
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)						