

Site Name:					
Pharmacy Site File – document version checklist					
Complete 'yes' or 'no' to confirm the presence or absence of each document specified.					
Document Name	Version	Date	Present?		Comments
1.1 TRIAL MANAGEMENT					
Contact List of CTC staff	2.0	28/09/2018	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Site Staff Delegation Log	2.0	19/07/2018	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Site Contacts Form	1.0	25/05/2018	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Record/Minutes of (internal) trial related meetings at Site	Site specific	N/A	Y <input type="checkbox"/>	N <input type="checkbox"/>	
1.2 PROTOCOL AND TRIAL INFORMATION					
Protocol - Current	3.0	06/08/2018	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Protocol – Superseded	2.0	03/01/2018	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Protocol Version History Log <i>(updated with current protocol version)</i>	N/A	N/A	Y <input type="checkbox"/>	N <input type="checkbox"/>	
1.3 IMP REFERENCE					
Current Version of IB(s): Avelumab (add file note if held electronically)	7	22/05/2017	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Superseded IBs	N/A	N/A	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Avelumab IB Receipts	N/A	N/A	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Avelumab IB Version History Log	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Current Version of IB(s): Cetuximab (add file note if held electronically)	23	April 2018	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Previous Version of SPC(s): Cetuximab (add file note if held electronically)	N/A	31/07/2017	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Cetuximab Previous Versions of IBs	N/A	N/A	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Cetuximab IB Receipts	3.0	05/03/2018	Y <input type="checkbox"/>	N <input type="checkbox"/>	
1.4 IMP HANDLING & DISPENSING PROCEDURES					
Summary of Drug Arrangements (SoDA)	2.0	22/08/2018	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Pharmacy Procedures <i>(e.g. pharmacy dispensing / trial specific guidelines)</i>	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Registration/ Randomisation Notifications	N/A	N/A	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Pharmacy Procedure for Temperature Monitoring & Reporting Temperature Excursions	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Destruction Procedure	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
1.5 TRIAL AUTHORISATIONS					
MHRA CTA Approval	N/A	09/01/2018	Y <input type="checkbox"/>	N <input type="checkbox"/>	
HRA Approval	N/A	26/03/2018	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Relevant Approvals for Amendments	N/A	N/A	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Site Activation Letter	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	

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5. AGREEMENTS AND CONTRACTS					
Signed Clinical Trial Site Agreement (CTSA)	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Completed Site Registration Form	1.0	09/03/2018	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Site Activation Letter	N/A	20/07/2018	Y <input type="checkbox"/>	N <input type="checkbox"/>	
2.0 PHARMACY STAFF					
Current CV and evidence of GCP training for main pharmacy staff	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Site Initiation Training Slides	1.0	25/05/2018	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Site Initiation Report & Attendee Log	N/A	N/A	Y <input type="checkbox"/>	N <input type="checkbox"/>	Provided by UCL CTC after SIV
Internal pharmacy Signature Log	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
3.0 TEMPLATES					
Prescriptions	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Approved IMP Labels	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Required Dispensing Label Information	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Accountability Logs - Avelumab	1.0	05/04/2018	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Accountability Logs - Cetuximab	1.0	05/04/2018	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Stock Balance Logs - Avelumab	1.0	04/04/2018	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Stock Balance Logs - Cetuximab	1.0	04/04/2018	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Drug Order Form- Avelumab	N/A	N/A	Y <input type="checkbox"/>	N <input type="checkbox"/>	Provided by UCL CTC on 28/01/2019
Drug Order Form- Cetuximab	N/A	N/A	Y <input type="checkbox"/>	N <input type="checkbox"/>	Provided by UCL CTC on 28/01/2019
UCL CTC Incident Report Template	2.0	25/06/15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
UCL CTC Temperature Excursion Template	1.1	27/02/2013	Y <input type="checkbox"/>	N <input type="checkbox"/>	
4.0 STORAGE					
Temperature Logs (or file note indicating location)	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Completed Notification of Temperature Excursion Forms (those reported to CTC)	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Details of Temperature Monitoring System including location of maintenance and calibration certificates	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
5.0 AVELUMAB					

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Completed Drug Order Forms	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Shipment/receipt documentation (QP release and certificate of analysis, etc.)	N/A	N/A	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Stock Balance Log	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Destruction Certificates	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Recall Notices	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
6.0 CETUXIMAB					
Completed Drug Order Forms	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Shipment/receipt documentation (QP release and certificate of analysis, etc.)	N/A	N/A	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Stock Balance Log	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Destruction Certificates	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Recall Notices	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
7.0 PATIENTS					
Master Subject List	1.0	09/04/2018	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Completed Prescriptions – Avelumab and Cetuximab	N/A	N/A	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Patient Accountability Logs – Avelumab and Cetuximab	N/A	N/A	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Aseptic/Preparation Worksheets – Avelumab and Cetuximab	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
8.0 SPONSOR MONITORING ACTIVITIES					
On-site Monitoring Visit Correspondence	N/A	N/A	Y <input type="checkbox"/>	N <input type="checkbox"/>	
On-Site Monitoring Visit - Site Visit Log	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
On-site Monitoring Visit – Pharmacy actions	Site specific	Site specific	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Responses to On-Site Monitoring Visit Actions (signed and dated)	N/A	N/A	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Central Monitoring Requests/Correspondence/Completed PSF Checklists	N/A	N/A	Y <input type="checkbox"/>	N <input type="checkbox"/>	
9.0 CORRESPONDENCE					
All correspondence filed	N/A	N/A	Y <input type="checkbox"/>	N <input type="checkbox"/>	

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10.0 END OF TRIAL				
Trial and Site Closure Documents and Correspondence	N/A	N/A	Y <input type="checkbox"/> N <input type="checkbox"/>	
Please provide the email address of the person to whom updated documents should be sent:				
<p>The completed form can be returned to ctc.each@ucl.ac.uk or faxed to 020 7679 9871 .</p> <p>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 is up-to-date.</p> <p>The following are general reminders regarding maintenance of the Investigator/Pharmacy Site File:</p> <p>The folder must be stored in a secure location with appropriate/restricted access.</p> <p>The documents should be filed as per index. <i>(CTC index or site's own index is acceptable)</i></p> <p>Documents generated locally (e.g. local approvals, lab normal ranges, correspondence, etc.) must be filed in the applicable sections.</p> <p>Where documents are held in an alternative location, file notes should be present to indicate this.</p> <p>Up-to-date CVs must be present for all site staff. <i>(CVs should be current at the time the trial is opened, be kept up to date and be signed and dated)</i></p> <p>GCP certificates must be present (or details of course attended listed in the CV) for all site staff. <i>(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). CVs/GCP certificates stored in an alternative location must be made available when required and archived in the PSF at the end of the trial.</i></p>				