

Pharmacy Site File Index and Self-Assessment Checklist

Please complete this form and return it to the RAMPART trial management team prior to your pharmacy initiation teleconference. This form should then be updated as applicable, and should be filed in your pharmacy site file.

Please fax/email a signed and dated copy to:

RAMPART Trial Team

Email: mrcctu.rampart@ucl.ac.uk

Fax: 0207 670 4818

A copy of all current pharmacy and main site file content can also be found on the RAMPART website

(<https://www.rampart-trial.org/members-area/>)

Centre Name	Centre Number	Lead pharmacist

Site File Key
Provided by RAMPART team: no action required
Provided by RAMPART team: some action required
Provided by your centre: file as appropriate

	Version/Date (where applicable)	In site file			Key
		Y	N	NA	
1.0 PROTOCOL					
Current protocol	2.0, 18-Apr-2019	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2.0 PRODUCT INFORMATION					
Durvalumab Investigator Brochure	14.0, 11-Feb-2019	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Tremelimumab Investigator Brochure	9.0, 27-Nov-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.0 IMP MANAGEMENT					
Pharmacy Manual					
RAMPART Pharmacy Manual	2.0, 20-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Drug Supply Management Systems Instructions	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Packaging and Labelling					
Durvalumab Sample Approved Label (carton)	2.0, 08-Jan-2019	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Durvalumab Sample Approved Label (vial)	2.0, 08-Jan-2019	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Tremelimumab Sample Approved Label (carton)	2.0, 08-Jan-2019	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Tremelimumab Sample Approved Label (vial)	2.0, 08-Jan-2019	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Study Drug Supply/Shipping					
Drug Delivery Receipt Forms		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
QP Release		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Storage					
Temperature Logs/File Note on temperature control system		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Notification of Temperature Deviation		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Dispensing					
Dispensing Guidelines					
Master Prescription					
Completed Prescriptions					

		In site file			Key
Accountability/Destruction					
Accountability Logs					
Destruction Logs					
Randomisation					
Randomisation confirmations (sent by trial team upon randomisation)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.0 SITE STAFF	Version (where applicable)	Y	N	NA	
Delegation of Responsibilities Log	2.0, 27-Sep-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Site Personnel List	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CVs and GCP certificates		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5.0 TOOLS AND TEMPLATES	Version (where applicable)	Y	N	NA	
Pharmacy Site File index and self-assessment checklist (<i>this document</i>)	2.0, 20-May-2019	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pharmacy Declaration	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Site Activation Checklist	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6.0 CORRESPONDENCE	Version (where applicable)	Y	N	NA	
Emails and Letters		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
File Notes		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7.0 MONITORING	Version (where applicable)	Y	N	NA	
Monitoring Reports		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8.0 TRAINING	Version (where applicable)	Y	N	NA	
RAMPART Training slides		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
RAMPART Training Log	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9.0 MISCELLANEOUS	Version (where applicable)	Y	N	NA	
<<Add here as appropriate>>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

I/We confirm that the above documents are stored in the RAMPART Pharmacy file		
Print Name		Date:
Signature		
Job title		