

Investigator Site File Self-Assessment Form

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

Centre Name	Centre Number	First Point of Contact

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 the Site File?			Key
		Y	N	NA	
1.0 PROTOCOL					
Protocol	1.0, 22-Nov-2017	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2.0 PRODUCT INFORMATION					
Durvalumab Investigator Brochure	11.0, 28-Apr-2017	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Tremelimumab Investigator Brochure	7.0, 07-Jun-2016	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.0 GUIDANCE DOCUMENTS					
RAMPART Guide	1.0, 31-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"/>	
Image Repository User Guide	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.0 SAMPLE CASE REPORT FORMS					
CRF Completion Guidelines	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Randomisation CRF (Form 1)	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Eligibility CRF (Form 2)	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Surgery CRF (Form 3)	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Concomitant Medications Log (Form 4)	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Treatment CRF (Form 5)	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
AE Log (Form 6)	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Tremelimumab End of Treatment CRF (Form 7A)	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Durvalumab End of Treatment CRF (Form 7B)	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Post-Treatment CRF (Form 8)	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Disease Assessment CRF (Form 9)	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Progression CRF (Form 10)	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

		In the Site File?			Key
Death CRF (Form 12)	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
SAE CRF (Form 13)	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pregnancy Monitoring CRF (Form 14)	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
EQ-5D Questionnaire (Form 15)	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
QLQ-C30 Questionnaire (Form 16)	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pathology CRF (Form 17)	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Medical History CRF (Form 18)	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5.0 PARTICIPANT DOCUMENTS	Version (where applicable)	Y	N	NA	
Participant Information Sheet	1.0, Oct-2017	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participant Consent Form	1.0, Oct-2017	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
GP Letter	1.0, Oct-2017	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pregnant Partner Information Sheet	1.0, Dec-2017	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pregnant Partner Consent Form	1.0, Dec-2017	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6.0 APPROVALS	Version/Date (where applicable)	Y	N	NA	
R&D					
Confirmation of Capability & Capacity		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MHRA					
CTA Application Cover Letter	13-Oct-2017	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Non-Acceptance Letter	08-Nov-2017	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Response to Non-Acceptance	22-Nov-2017	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Clinical Trials Authorisation	24-Nov-2017	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
HRA					
HRA Application Cover Letter	12-Oct-2017	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Initial Assessment Letter	03-Nov-2017	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Letter of HRA Approval	08-Jan-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Schedule of Events	V2.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Statement of Activities	V1.0, 12-Oct-2017	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
REC					
REC Application Cover Letter	12-Oct-2017	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Provisional Opinion Letter	16-Nov-2017	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Response to Provisional Opinion	15-Dec-2017	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Favourable Opinion Letter	07-Jan-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7.0 INSURANCE	Version (where applicable)	Y	N	NA	
UCL Insurance Statement	Aug-2017	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8.0 AGREEMENTS	Version (where applicable)	Y	N	NA	
Model non-commercial agreement	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

		In the Site File?			Key
9.0 SITE STAFF	Version (where applicable)	Y	N	NA	
Delegation of Responsibilities Log	1.0, 31-May-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"/>	
Principal Investigator Statement	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"/>	
10.0 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"/>	
11.0 TOOLS AND TEMPLATES	Version (where applicable)	Y	N	NA	
Investigator Site File Self-Assessment Checklist	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"/>	
12.0 PATIENT RECORDS	Version (where applicable)	Y	N	NA	
Participant List	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Screening Log	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Signed Consent Forms		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
13.0 SAFETY REPORTING	Version (where applicable)	Y	N	NA	
SAE Log	1.0, 31-May-2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
SAE Reports		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Annual Safety Reports		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
14.0 MONITORING	Version (where applicable)	Y	N	NA	
Monitoring Reports					
15.0 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"/>	
16.0 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 Investigator Site File		
Print Name		Date:
Signature		
Job title		