PHARMACY DECLARATION

ISRCTN:	53348826
EudraCT:	2017-002329-39
Investigational Medicinal Product:	Durvalumab Tremelimumab
Marketing Authorisation Holder :	Astra Zeneca UK
Site Name:	
Site Number:	
Principal Investigator:	
Lead Pharmacist:	

I confirm that:	**Initial to confirm**
I am in receipt of the RAMPART Pharmacy Pack, including the current IBs (shared electronically prior to site activation)	
I am in receipt of the RAMPART Pharmacy Site File	
I have are reviewed the current RAMPART Protocol	
I have reviewed the RAMPART Pharmacy Manual	

I agree to comply with the requirements outlined below:
To segregate study supplied drug from other non-study drug
To maintain all documents and study drug in a secure/locked area.
To maintain all stock in a temperature-controlled environment and report any deviations to the study team
To ensure the study drug will be dispensed to RAMPART participants only upon receipt of a written prescription by an investigator listed on the Site Delegation log
To follow the procedures outlined in the RAMPART Pharmacy Manual and, where appropriate, to establish site-specific written plan for receiving, preparing and dispensing prescriptions of study drug
To ensure all Pharmacy personnel involved in any of the trial-related procedures will: • Be trained on the study procedures • Be included in the delegation log
To notify the RAMPART study team when changes in Pharmacy personnel occur
To maintain and keep up to date the following documents and any other documents necessary to dispense study drug in a safe manner in accordance with the protocol: • Pharmacy Site File, including but not limited to the RAMPART Protocol and Pharmacy Manual • Orders/shipment receipt confirmation /QP releases • Written prescriptions and/or written documentation concerning the validation of the electronic prescription systems • Temperature logs • Accountability records • Destruction records • Current signature delegation logs for investigator and sub-investigators • Copies of pharmacy monitoring documents and reports
To maintain confidentiality of patient pharmacy files and the accountability records
To make accessible all pharmacy records in the event of an audit by the study sponsors, local regulatory agencies and other regulatory agencies or their designees.

Signature of Lead Pharmacist for Site _____

Date _____