

Patient Information Version History

Name of Trial: **ANIMATE:** A phase II study of nivolumab monotherapy in patients with relapsed/refractory Hodgkin lymphoma, fit for autologous stem cell transplant, who fail to reach complete metabolic remission after first or second line salvage therapy

Name of Chief Investigator: Dr Graham Collins

Document (PIS, Consent Form, GP Letter, Patient Card etc.)	Version Number	Date	Main changes	REC Approval Date	Date of distribution to sites
Previous versions					
PIS	1.0	04.01.2018	N/A Initial version	27.02.2018	
ICF	1.0	04.01.2018	N/A Initial version	27.02.2018	
Pregnancy Monitoring IS (partners)	1.0	04.01.2018	N/A Initial version	27.02.2018	
Pregnancy Monitoring ICF (partners)	1.0	04.01.2018	N/A Initial version	27.02.2018	
GP letter	1.0	04.01.2018	N/A Initial version	27.02.2018	
PIS	2.0	10.04.2018	Change of central labs listed	30.04.2018	
ICF	2.0	10.04.2018	Change of central labs listed	30.04.2018	
PIS	3.0	12.06.2018	See tracked version	13.08.2018, reissued 30.08.2018	
ICF	3.0	12.06.2018	See tracked version	13.08.2018, reissued 30.08.2018	
PIS	4.0	10.12.2019	See tracked version	15.01.2020	
ICF	4.0	10.12.2019	See tracked version	15.01.2020	
Current versions					
Patient Contact Card Current	1.0	04.01.2018	N/A Initial version	27.02.2018	
GP letter Current	2.0	10.12.2019	See tracked version	15.01.2020	
Pregnancy Monitoring IS (partners) Current	2.0	12.06.2018	See tracked version	13.08.2018, reissued 30.08.2018	
Pregnancy Monitoring ICF (partners) Current	2.0	12.06.2018	See tracked version	13.08.2018, reissued 30.08.2018	
Pregnancy Monitoring IS (patients) Current	1.0	28.05.2020	N/A Initial version	07.07.2020	10.07.2020
Pregnancy Monitoring ICF (patients) Current	1.0	28.05.2020	N/A Initial version	07.07.2020	10.07.2020
PIS Current	5.0	28.05.2020	Updated RSI (IB v18) & pt videos	07.07.2020	10.07.2020
ICF Current	4.1	28.05.2020	Section 11 replaced 'trial' with 'child'	07.07.2020	10.07.2020