Case Report Form

STUDY TITLE

Chief / Principal Investigator:

CRF Version Number: V / /20

UoL Reference Number:

UHL/CRN Reference Number:

Subject ID Number: | | | |

Subject Initials: | | | |

Sponsor:
University of Leicester
Research Governance Office
Research & Enterprise Division
Fielding Johnson Building
University Road
Leicester
LE1 7RH

Subject ID:	Subject Initials:	Visit Date:
		D D M M Y Y

VISIT 1 SCREENING Demographic Data

Date of Birth	D D M M Y Y			
Ethnicity				
White	White British ☐	White Irish ☐	White Other ☐	
Mixed Race	White & Black Caribbean ☐	White & Black African ☐	White & Asian ☐	Other mixed background ☐
Asian or Asian British	Indian ☐	Bangladeshi ☐	Pakistani ☐	Other Asian background ☐
Black or Black British	Caribbean ☐	African ☐	Black Other ☐	
Chinese or other ethnicity	Chinese ☐	Other ☐ (please specify)		

Gender	☐ Male	☐ Female

Completed by: Signature: Date:

Subject ID:	Subject Initials:	Visit Date:
		D D M M Y Y

VISIT 1 SCREENING Informed Consent Process

Informed Consent Process		
Date & Time subject/relative/witness given Participant Information Sheet	Date D D M M Y Y	Time H H M M
Date & Time subject/relative/witness signed Written Consent Form	Date D D M M Y Y	Time H H M M
Date & Version Number of Participant Information Sheet consented to	Date D D M M Y Y	Version v .....
Name of person taking Informed Consent	Name _____	
Has a copy of the signed consent form/participant information sheet been given to the subject?	Yes ☐ No ☐	At time of consent Yes ☐ No ☐ Posted to subject Yes ☐ No ☐ Date posted D D M M Y Y If not please explain .....
Has a copy of the signed consent form/participant information sheet been filed in the medical notes?	Yes ☐ No ☐	If not please explain .....
Has a written entry detailing the consent process been made in the main body of the medical notes?	Yes ☐ No ☐	If not please explain .....

Completed by: Signature: Date:

Subject ID:	Subject Initials:	Visit Date:
		D D M M Y Y

VISIT 1 SCREENING Inclusion Criteria

Date of Assessment	D D M M Y Y

Inclusion Criteria				
		YES	NO	N/A
1.	*INSERT INCLUSION CRITERIA AS PER PROTOCOL*	☐	☐	☐
2.		☐	☐	☐
3.		☐	☐	☐
4.		☐	☐	☐
5.		☐	☐	☐
6.		☐	☐	☐
7.		☐	☐	☐
8.		☐	☐	☐
9.		☐	☐	☐
10.		☐	☐	☐
If any of the above criteria is answered NO, the subject is not eligible for the trial and must not be included in the study.				

Completed by: Signature: Date:

Subject ID:	Subject Initials:	Visit Date:
		D D M M Y Y

VISIT 1 SCREENING Exclusion Criteria

Date of Assessment	D D M M Y Y

Exclusion Criteria			
		YES	NO
1.	*INSERT EXCLUSION CRITERIA AS PER PROTOCOL*	☐	☐
2.		☐	☐
3.		☐	☐
4.		☐	☐
5.		☐	☐
6.		☐	☐
7.		☐	☐
8.		☐	☐
9.		☐	☐
10.		☐	☐
If any of the above criteria is answered YES, the subject is not eligible for the trial and must not be included in the study.			

Completed by: Signature: Date:

UNIVERSITY OF LEICESTER

Subject ID:	Subject Initials:	Visit Date:
☐☐☐	☐☐☐	D D / M M / Y Y
VISIT 1 SCREENING Medical History		

Medical History			
Has the subject had any relevant medical history?	No ☐ Yes ☐ complete below If not please explain …………………………… ……………………………………………………………		
Date of Assessment	D D M M Y Y		
Condition/Illness / Surgical Procedure	Start Date (DD/MM/YYYY)	Stop Date (DD/MM/YYYY)	OR tick if on going at screening visit
	____/ ____/______	____/ ____/______	☐
	____/ ____/______	____/ ____/______	☐
	____/ ____/______	____/ ____/______	☐
	____/ ____/______	____/ ____/______	☐
	____/ ____/______	____/ ____/______	☐
	____/ ____/______	____/ ____/______	☐
	____/ ____/______	____/ ____/______	☐
	____/ ____/______	____/ ____/______	☐
	____/ ____/______	____/ ____/______	☐
	____/ ____/______	____/ ____/______	☐
	____/ ____/______	____/ ____/______	☐
	____/ ____/______	____/ ____/______	☐
	____/ ____/______	____/ ____/______	☐

Completed by: Signature: Date:

Subject ID:	Subject Initials:	Visit Date:
		D D M M Y Y

VISIT 1 SCREENING Physical Examination

Physical Examination	
Was a physical examination performed?	No ☐ Yes ☐ complete below If not please explain …… ……
Date of examination	D D M M Y Y

System	*Abnormal	Normal	Not Done	if ABNORMAL, please provide brief description and record if clinically significant or not (CS/NCS)
General Appearance	☐	☐	☐	
Skin	☐	☐	☐	
Eyes, Ears, Nose & Throat	☐	☐	☐	
Head, Neck & Thyroid	☐	☐	☐	
Cardiovascular	☐	☐	☐	
Respiratory	☐	☐	☐	
Abdomen	☐	☐	☐	
Extremities	☐	☐	☐	
Genitalia	☐	☐	☐	
Anorectal	☐	☐	☐	
Lymph Nodes	☐	☐	☐	
Muscular-Skeletal	☐	☐	☐	
Neurological	☐	☐	☐	
Others (please specify)	☐	☐	☐	

Completed by: Signature: Date:

Subject ID:	Subject Initials:	Visit Date:
		D D M M Y Y

VISIT 1 SCREENING Vital Signs & ECG

Vital Signs & ECG	
Were vital signs performed?	No ☐ Yes ☐ complete below If not please explain …… ……
Date of Vital Signs	D D M M Y Y
Time of Vital Signs	H H M M
Blood Pressure supine/standing/seated ___ ___ ___ / ___ ___ ___ mmHG	
Pulse ___ ___ ___ beats/min	
Weight ___ ___ ___ . ___ kg Height ___ . ___ ___ m	
Temperature ___ ___ . ___ °c	
Was an ECG performed? No ☐ Yes ☐ complete below If not please explain ……	
Date ECG performed	D D M M Y Y
Time ECG performed	H H M M
The ECG is	☐ Within normal limits ☐ Abnormal, NOT clinically significant ☐ Abnormal, Clinically Significant, please specify: …… ……

Completed by: Signature: Date:

Completed by: Signature: Date:

Subject ID:	Subject Initials:	Visit Date:
		D D M M Y Y

VISIT 1 (SCREENING) Haematology

Haematology	
Clinical Haematology Laboratory tests performed?	No ☐ Yes ☐ complete below If not please explain …… ……
Date of Sample	D D M M Y Y
Time of Sample	H H M M

Haematology	Value	Unit	If indicated as out of normal range on report, please state if clinically significant
WBC			No ☐ Yes ☐
RBC			No ☐ Yes ☐
Hb			No ☐ Yes ☐
HCT			No ☐ Yes ☐
MCV			No ☐ Yes ☐
MCH			No ☐ Yes ☐
PLT			No ☐ Yes ☐
NEUTROPHILS			No ☐ Yes ☐
LYMPHOCYTES			No ☐ Yes ☐
MONOCYTES			No ☐ Yes ☐
EOSINOPHILS			No ☐ Yes ☐
BASOPHILS			No ☐ Yes ☐
RETICULOCYTES			No ☐ Yes ☐

Completed by: Signature: Date:

Subject ID:	Subject Initials:	Visit Date:
		D D M M Y Y

VISIT 1 SCREENING Biochemistry

Biochemistry	
Clinical Biochemistry Laboratory tests performed?	No ☐ Yes ☐ complete below If not please explain ……. ……
Date of Sample	D D M M Y Y
Time of Sample	H H M M

Biochemistry	Value	Unit	If indicated as out of normal range on report, please state if clinically significant
SODIUM			No ☐ Yes ☐
POTASSIUM			No ☐ Yes ☐
CHLORIDE			No ☐ Yes ☐
BICARBONATE			No ☐ Yes ☐
UREA			No ☐ Yes ☐
CREATININE			No ☐ Yes ☐
TOTAL PROTEIN			No ☐ Yes ☐
TOTAL BILIRUBIN			No ☐ Yes ☐
ALBUMIN			No ☐ Yes ☐
ALK PHOS			No ☐ Yes ☐
ALT			No ☐ Yes ☐
AST			No ☐ Yes ☐
CALCIUM			No ☐ Yes ☐

Completed by: Signature: Date:

Subject ID:	Subject Initials:	Visit Date:
		D D M M Y Y

VISIT 1 SCREENING *Insert Assessment*

INSERT ASSESSMENT	
Clinical *INSERT ASSESSMENT* Laboratory tests performed?	No ☐ Yes ☐ complete below If not please explain …… ……
Date of Sample	D D M M Y Y
Time of Sample	H H M M

INVESTIGATOR TO INSERT OTHER ASSESSMENT	Value	Unit	If indicated as out of normal range on report, please state if clinically significant
			No ☐ Yes ☐
			No ☐ Yes ☐
			No ☐ Yes ☐
			No ☐ Yes ☐
			No ☐ Yes ☐
			No ☐ Yes ☐
			No ☐ Yes ☐
			No ☐ Yes ☐
			No ☐ Yes ☐
			No ☐ Yes ☐
			No ☐ Yes ☐
			No ☐ Yes ☐
			No ☐ Yes ☐

Completed by: Signature: Date:

Subject ID:	Subject Initials:	Visit Date:
		D D M M Y Y

VISIT 1 SCREENING Screening Concomitant Medication

Concomitant Medications							
Date of Assessment		D D M M Y Y					
Is the subject taking any concomitant medications?		No ☐ Yes ☐ complete below					
Medication	Reason for use	Dose & Units	Frequency	Route	Start Date (DD/MM/YYYY)	Stop Date (DD/MM/YYYY)	OR tick if on going at time of screening visit
1.					__/__ /__	__/__ /__	☐
2.					__/__ /__	__/__ /__	☐
3.					__/__ /__	__/__ /__	☐
4.					__/__ /__	__/__ /__	☐
5.					__/__ /__	__/__ /__	☐
6.					__/__ /__	__/__ /__	☐
7.					__/__ /__	__/__ /__	☐
8.					__/__ /__	__/__ /__	☐
9.					__/__ /__	__/__ /__	☐
10.					__/__ /__	__/__ /__	☐
11.					__/__ /__	__/__ /__	☐
12.					__/__ /__	__/__ /__	☐

Completed by: Signature: Date:

Subject ID:	Subject Initials:	Visit Date:
		D D M M Y Y

VISIT 1 SCREENING Smoking / Alcohol

Date of Assessment	D D M M Y Y

Smoking / Alcohol	
Has the subject ever smoked?	No ☐ Yes ☐ complete below
☐ Current Smoker	Subject's average daily use: Number smoked per day ___ ___
☐ Former Smoker	Smoked for ___ ___ months / years Date when smoking ceased D D M M Y Y
Participants alcohol consumption Wine ___ ___ units per week / month Beer ___ ___ units per week / month Spirits ___ ___ units per week / month	

Completed by: Signature: Date:

Subject ID:	Subject Initials:	Visit Date:
		D D M M Y Y

VISIT 1 SCREENING Subject Eligibility Review

Date of Assessment	D D M M Y Y

Participant Eligibility Review			
		YES	NO
1.	Does the subject satisfy the inclusion/exclusion criteria?	☐	☐
2.	Have the medical history and concomitant medication pages been completed?	☐	☐
3.	Is the subject still willing to proceed in the trial?	☐	☐

Subject's eligibility Investigator sign-off	
Is the subject eligible to take part in the Clinical Trial? Principal Investigator's (or delegated individual*) Signature: _____ Date: __ __ / __ __/ __ __ __ __ (DD/MM/YYYY) Investigator's Name: _____ *Must be reflected in the Delegation of Authority Log	☐ YES ☐ NO Please give reason below

Reason(s) for screen failure
1.
2.
3.

Subject Randomisation/Enrolment	
Subject Study Number Allocated	Subject ID ___ ___ ___
Date of Randomisation/Enrolment	D D M M Y Y

Completed by: Signature: Date:

Subject ID:	Subject Initials:	Visit Date:
		D D M M Y Y

VISIT 1 SCREENING Investigational Medicinal Product

Date of Assessment	D D M M Y Y

Investigational Medicinal Product			
		YES	NO
1.	Has the subject been issued with the Trial Medication as per protocol?	☐	☐ If NOT explain ……
2.	Has the subject received instruction / guidance on how to take the Trial Medication?	☐	☐ If NOT explain

Randomisation		
Subject randomised to:	Arm *INSERT AS PER PROTOCOL* ☐	Arm *INSERT AS PER PROTOCOL* ☐

Completed by: Signature: Date:

Subject ID:	Subject Initials:	Visit Date:
		D D M M Y Y

VISIT *INSERT VISIT NAME OR NUMBER AS PER PROTOCOL* Checklist

Visit Checklist			
		YES	NO
1.	Did the subject experience any new or changes to existing adverse events since the screening visit/previous visit? If YES, please complete adverse event page *(If an AE is marked as serious this must be reported to the Sponsor within 24 hours of the research team being made aware of the event, utilising the Sponsor SAE form as per Sponsor SOP S-1009)*	☐	☐
2.	Have there been any changes to existing medication, or the subject has taken any new medication since the screening visit/previous visit? If YES, please complete concomitant medication page	☐	☐
3.	*INVESTIGATOR TO ADD OTHER REQUIRED ASSESSMENTS AS PER PROTOCOL*	☐	☐
4.		☐	☐

Completed by: Signature: Date:

Subject ID:	Subject Initials:	Visit Date:
		D D M M Y Y

VISIT *INSERT VISIT NAME OR NUMBER AS PER PROTOCOL* Physical Examination

Physical Examination	
Was a physical examination performed?	No ☐ Yes ☐ complete below If not please explain …….. ……
Date of examination	D D M M Y Y

System	*Abnormal	Normal	Not Done	*if noted ABNORMAL, please provide brief description and comment if clinically significant or not (CS/NCS)
General Appearance	☐	☐	☐	
Skin	☐	☐	☐	
Eyes, Ears, Nose & Throat	☐	☐	☐	
Head, Neck & Thyroid	☐	☐	☐	
Cardiovascular	☐	☐	☐	
Respiratory	☐	☐	☐	
Abdomen	☐	☐	☐	
Extremities	☐	☐	☐	
Genitalia	☐	☐	☐	
Anorectal	☐	☐	☐	
Lymph Nodes	☐	☐	☐	
Muscular-Skeletal	☐	☐	☐	
Neurological	☐	☐	☐	
Others (please specify)	☐	☐	☐	

Completed by: Signature: Date:

Subject ID:	Subject Initials:	Visit Date:
		D D M M Y Y

VISIT *INSERT VISIT NAME OR NUMBER AS PER PROTOCOL* Vital Signs

Vital Signs & ECG	
Were vital signs performed?	No ☐ Yes ☐ complete below If not please explain …… ……
Date of Vital Signs	D D M M Y Y
Time of Vital Signs	H H M M
Blood Pressure supine/standing/seated ___ ___ ___ / ___ ___ ___ mmHG	
Pulse ___ ___ ___ beats/min	
Weight ___ ___ ___ . ___ kg Height ___ . ___ ___ m	
Temperature ___ ___ . ___ °c	
Was an ECG performed? No ☐ Yes ☐ complete below If not please explain ……	
Date ECG performed	D D M M Y Y
Time ECG performed	H H M M
The ECG is	☐ Within normal limits ☐ Abnormal, NOT clinically significant ☐ Abnormal, Clinically Significant, please specify: …… ……

Completed by: Signature: Date:

Subject ID:	Subject Initials:	Visit Date:
		D D M M Y Y

VISIT *INSERT VISIT NAME OR NUMBER AS PER PROTOCOL* Haematology

Haematology	
Clinical Haematology Laboratory tests performed?	No ☐ Yes ☐ complete below If not please explain …… ……
Date of Sample	D D M M Y Y
Time of Sample	H H M M

Haematology	Value	Unit	If indicated as out of normal range on report, please state if clinically significant
WBC			No ☐ Yes ☐
RBC			No ☐ Yes ☐
Hb			No ☐ Yes ☐
HCT			No ☐ Yes ☐
MCV			No ☐ Yes ☐
MCH			No ☐ Yes ☐
PLT			No ☐ Yes ☐
NEUTROPHILS			No ☐ Yes ☐
LYMPHOCYTES			No ☐ Yes ☐
MONOCYTES			No ☐ Yes ☐
EOSINOPHILS			No ☐ Yes ☐
BASOPHILS			No ☐ Yes ☐
RETICULOCYTES			No ☐ Yes ☐

Completed by: Signature: Date:

Subject ID:	Subject Initials:	Visit Date:
		D D M M Y Y

VISIT *INSERT VISIT NAME OR NUMBER AS PER PROTOCOL* Biochemistry

Biochemistry	
Clinical Biochemistry Laboratory tests performed?	No ☐ Yes ☐ complete below If not please explain …… ……
Date of Sample	D D M M Y Y
Time of Sample	H H M M

Biochemistry	Value	Unit	If indicated as out of normal range on report, please state if clinically significant
SODIUM			No ☐ Yes ☐
POTASSIUM			No ☐ Yes ☐
CHLORIDE			No ☐ Yes ☐
BICARBONATE			No ☐ Yes ☐
UREA			No ☐ Yes ☐
CREATININE			No ☐ Yes ☐
TOTAL PROTEIN			No ☐ Yes ☐
TOTAL BILIRUBIN			No ☐ Yes ☐
ALBUMIN			No ☐ Yes ☐
ALK PHOS			No ☐ Yes ☐
ALT			No ☐ Yes ☐
AST			No ☐ Yes ☐
CALCIUM			No ☐ Yes ☐

Completed by: Signature: Date:

Subject ID:	Subject Initials:	Visit Date:
		D D M M Y Y

VISIT *INSERT VISIT NAME OR NUMBER AS PER PROTOCOL* Trial Medication Accountability

INSERT ASSESSMENT	
Clinical *INSERT ASSESSMENT* Laboratory tests performed?	No ☐ Yes ☐ complete below If not please explain …….. ……..
Date of Sample	D D M M Y Y
Time of Sample	H H M M

INSERT ASSESSMENT	Value	Unit	If indicated as out of normal range on report, please state if clinically significant
			No ☐ Yes ☐
			No ☐ Yes ☐
			No ☐ Yes ☐
			No ☐ Yes ☐
			No ☐ Yes ☐
			No ☐ Yes ☐
			No ☐ Yes ☐
			No ☐ Yes ☐
			No ☐ Yes ☐
			No ☐ Yes ☐
			No ☐ Yes ☐
			No ☐ Yes ☐
			No ☐ Yes ☐

Completed by: Signature: Date:

Subject ID:	Subject Initials:	Visit Date:
		D D M M Y Y

VISIT *INSERT VISIT NAME OR NUMBER AS PER PROTOCOL* Trial Medication Accountability

Investigational Medicinal Product			
		YES	NO
1.	Has the subject been issued with the Trial Medication as per protocol?	☐	☐ If NOT explain ……
2.	Has the subject received instruction / guidance on how to take the Trial Medication?	☐	☐ If NOT explain

Trial Medication Returns			
	Trial Medication Name	Quantity Returned	Date of Return DD/MM/YYYY
1.			/ /
2.			/ /
3.			/ /
4.			/ /

Completed by: Signature: Date:

Subject ID:	Subject Initials:	Visit Date:
		D D M M Y Y

END OF TRIAL	
Date of trial completion/withdrawal	D D M M Y Y
Date last trial medication given	D D M M Y Y

Trial Participation Outcome	YES	NO
Completed trial	☐	☐
Withdrawn from trial (complete withdrawal form below)	☐	☐

Trial Withdrawal Form		
Reason for Withdrawal	YES	NO
Lost to follow up	☐	☐
Non-compliance	☐	☐
Concomitant medication	☐	☐
Medical contraindication	☐	☐
Consent withdrawn	☐	☐
AE/SAE/SUSAR (complete SAE form)	☐	☐
Death (complete SAE form)	☐	☐
Other (explain) …….. ……..	☐	☐

Chief/ Principal Investigator Sign Off

I ……(name)confirm that I have reviewed the case report form and confirm that to the best of my knowledge, the information contained within is accurate and complete.

Signature …….. Date / / DD/MM/YYYY

Completed by: Signature: Date:

Concomitant Medications Form	Subject ID:	Subject Initials:

Have there been any changes to existing medication, or the subject has taken any new medication since the screening visit? NO ☐ YES ☐ (record below)

	Medication name (Generic term preferred)	**Reason for use**	**Start Date** (DD/MM/YYYY)	**End Date** (DD/MM/YYYY)	**Dose**	**Unit**	**Route**	**Frequency**	**Continuing at the end of the study?**
1.			/ /	/ /					☐
2.			/ /	/ /					☐
3.			/ /	/ /					☐
4.			/ /	/ /					☐
5.			/ /	/ /					☐
6.			/ /	/ /					☐
7.			/ /	/ /					☐
8.			/ /	/ /					☐
9.			/ /	/ /					☐
10.			/ /	/ /					☐
11.			/ /	/ /					☐
12.			/ /	/ /					☐

Adverse Events Form	Subject ID	Subject Initials:

	Adverse Event Description	**Start Date** (DD/MMM/YYYY)	**End Date** (DD/MMM/YYYY)	**In case of SAE- Please specify the criteria** 1= Death 2 = Life threatening 3 = Hospitalisation 4 = Medically significant 5 = Congenital abnormality/birth defect	**Severity** 1= Mild 2 = Moderate 3= Severe	**Causality assessment** 1= Certain 2 = Probable/ Likely 3 = Possible Unlikely 4 = Conditional/ Unclassified 5 = Assessable/ Unclassifiable	**Action taken with trial treatment** 1=Dose modification 2=Discontinuation of the IMP 3= Not applicable 4 = Treatment continued without change	**Outcome** 1=Resolved 2=Resolved with sequelae 3= Ongoing 4= Fatal 5= Unknown
1.		/ /	/ /					
2.		/ /	/ /					
3.		/ /	/ /					
4.		/ /	/ /					
5.		/ /	/ /					
6.		/ /	/ /					
7.		/ /	/ /					
8.		/ /	/ /					
9.		/ /	/ /					
10.		/ /	/ /					
11.		/ /	/ /					
12.		/ /	/ /					