VISIT 1 SCREENING & ENROLLMENT (DAY 0)

DATE OF VISIT: 8-12-2017 (dd/mm/yyyy)

INFORMED CONSENT:

Has the written informed consent obtained (18 years and more) ☐ Yes ☒ No

Date of Informed Consent Obtained: 08.12.2017 (dd/mm/yyyy)

Has the written informed assent obtained (age 5-17 years) ☒ Yes ☐ No ☐ NA

Has audio-video recording of informed consent process taken? ☒ Yes ☐ No ☐ NA

DEMOGRAPHIC DETAILS:

DOB : 01 NOV 2017 01 — 08/12/17

Age : 1 6 (Years)

Gender : ☒ Male ☐ Female

Ethnicity :	☐ Hispanic or Latino	☒ Non- Hispanic or Latino
	☐ Unknown	☐ Not reported
	☐ Other, specify _____	
Race :	☐ White	☐ Native Hawaiian or Other Pacific Islander
	☒ Asian	☐ American Indian or Alaska Native
	☐ Black or African American	☐ Other, specify _____

Recorded By (sign and date): _____ 08/12/17

SHIVAM HOSPITAL REG. NO. 051201260 AHMEDABAD

SHIVAM HOSPITAL REG. NO. 051201260

MEDICAL /SURGICAL HISTORY:

☒ **None** (please Check the box if the subject doesn't have any Medical /Surgical history)

Is the Subject taking any medication for ongoing medical condition? ☐ Yes ☒ No
If, Yes please fill concomitant medication page

Sr. No.	Medical / Surgical history	Start date (DD-MMM-YYYY)	Stop date (DD-MMM-YYYY)	Ongoing
1	_____			☐
2	_____			☐
3	_____			☐
4	_____			☐
5	_____			☐

SHIVAM HOSPITAL REG. NO. 051201260 AHMEDABAD

MEDICATION HISTORY:

Sr. No.	Trade/ Generic Name	Route Code only	Frequency Code only	Indication	Start date dd/mmyyyy	Stop Date dd/mm/yyyy	Ongoing

Route: 1= Oral (P.O.), 2= Intramuscular, 3= Intravenous, 4= Topical, 5= Subcutaneous, 6= Other(specify)

Frequency: 1=Once Daily, 2=Twice Daily, 3=Thrice Daily, 4=Four Times Daily, 5=As and When Required

ABV 8/12/17

SHIVAM HOSPITAL REG. NO. 051201260 AHMEDABAD

PHYSICAL EXAMINATION:

Was the physical examination performed?	☒ Yes ☐ No
If No, Specify Reason: _____	ABV 08/12/17
If Yes, Date of Assessment	08 - DEC - 2017

Physical Examination	Result				
	*Not Done	Normal	Abnormal	If Abnormal (check one)	If Abnormal CS, please describe the abnormality
General Appearance	☐	☑	☐	☐CS ☐NCS	
Cardiovascular System	☐	☑	☐	☐CS ☐NCS	
Respiratory System	☐	☑	☐	☐CS ☐NCS	
Gastrointestinal System	☐	☑	☐	☐CS ☐NCS	
Musculoskeletal System	☐	☑	☐	☐CS ☐NCS	
Central Nervous System	☐	☑	☐	☐CS ☐NCS	
Reproductive System	☐	☑	☐	☐CS ☐NCS	
Other	☑	☐	☐	☐CS ☐NCS	
Other system (Except Not Done)					

Performed by (Name): Dr. P. H. Thakrani

Recorded by (Sign and date): 8/12/17

SHIVAM HOSPITAL REG. NO. 051201260 AHMEDABAD

VITAL SIGNS:		
Was the vital signs collected?	☑ Yes ☐ No	
Date of Assessment	08 - DEC - 2017	
Height (cm): 166.0	Weight (kg): 078.0	BMI (kg/m2): 28.3

Parameters	Result	Normal	Abnormal	If Abnormal (check one)	If Abnormal CS, please describe the abnormality
Systolic Blood Pressure	136 mmHg	☒	☐	☐CS ☐NCS	
Diastolic Blood Pressure	086 mmHg	☒	☐	☐CS ☐NCS	
Pulse rate	078 beats/min	☒	☐	☐CS ☐NCS	
Oral Temperature	098.9 °F	☒	☐	☐CS ☐NCS	
Respiratory rate	019 breaths/min	☒	☐	☐CS ☐NCS	

Recorded By (Sign and date): Vishakha 8/12/17

ECG DETAILS:		
Was ECG performed? ☒ Yes ☐ No		
Date of ECG Assessment: 08 - DEC - 2017	Time of ECG Assessment: 11 : 04 (24 hours format)	
Result?	☒ Normal	☐ Abnormal
If Abnormal, Clinically significant?	☐ Yes	☐ No
If Yes*, please specify _____		
Recorded By (Sign and date): 08/12/17		

SHIVAM HOSPITAL REG. NO. 051201260

ALCOHOL HISTORY:
Usage: ☐Past History ☐*Regular ☐Occasional ☒Never
If *Regular please specify : ☐☐Unit/day
Has subject agreed to follow alcohol restriction as per protocol? ☐Yes ☐No
Recorded By (Sign and date): ABV 08/12/17

URINE PREGNANCY TEST	
Pregnancy test performed?	☐ Yes ☐ No ☒ Not Applicable (Male)
If yes, Date of Pregnancy test	☐☐:☐☐☐:☐☐☐☐ (DD-MMM-YYYY)
Result	☐ Positive ☐ Negative
If No specify reason	☐ Post-Menopausal ☐ Surgically Sterile
If Postmenopausal since	☐☐:☐☐☐:☐☐☐☐ (DD-MMM-YYYY)
Recorded by (Sign and date): ABV 08/12/17	

CONTRACEPTIV METHOD:	
Contraceptive method used	☒Yes ☐No ☒Not Applicable
If Yes, describe the method	Male contraception (Using of condom)
If No or Not applicable, please specify the reason	~~Patient is Minor~~
Recorded By (Sign and date): ABV 08/12/17	

ABV 08/12/17

SHIVAM HOSPITAL REG. NO. 051201260 AHMEDABAD

LABORATORY ASSESSMENT	
Date of blood sample collection: 08-DEC-2017	Time: 11:10
Date of urine sample collection: 08-DEC-2017	Time: 11:15
Overall Assessment	☐ Normal ☒ Abnormal NCS ☐ Abnormal CS
Sample Repeated	☐ Yes ☒ No
If Yes, Date of repeat sample collection	☐☐:☐☐☐:☐☐☐☐ (DD-MMM-YYYY)
If Yes, Time of repeat sample collection	☐☐:☐☐ (HH:MM)
If Yes, Panel repeated	☐ Hematology ☐ Biochemistry ☐ Urinalysis ☐ Immunology
If Yes, Overall Assessment	☐ Normal ☐ Abnormal NCS ☐ Abnormal CS
Recorded by(Sign and Date): ABV 8/12/17	

IMMUNOGENICITY ASSESSMENT:	
Date of sample Collection	08-DEC-2017
Comments if, any:	

RVNA ASSESSMENT:	
Date of sample Collection	08-DEC-2017
Comments if, any:	

SHIVAM HOSPITAL REG. NO 051201260 AHMEDABAD

INCLUSION CRITERIA:					
Sr. No.	Criteria	Yes		No	
1.	Male and Female patient aged 5 years or more than 5 years.	☒		☐	
2.	WHO Category III exposure(s) by a suspected rabid animal.	☒		☐	
3.	Have documented informed consent from individuals, the child's parent(s) or legal guardian(s) and assent from the child if appropriate.	☒		☐	
4.	Free of obvious health problems as determined by history and examination.	☒		☐	
5.	If female, not pregnant or lactating at the time of enrolment and not planning pregnancy during the vaccination period.	☐	NA ☒	☐	
6.	Male subject must be agree to use at least one effective contraceptive method through out the entire duration of the study.	☐	NA ☒	☐	

EXCLUSION CRITERIA:					
SR. No.	Criteria	Yes		No	
1.	Pregnant and lactating women.	☐	NA ☒	☐	
2.	Patient has received any dose of rabies vaccines / rabies immunoglobulin in the past.	☐		☒	
3.	Allergic to any of the vaccine component / human rabies immunoglobulin components.	☐		☒	
4.	Chronic administration of immune suppressants or other immune-modifying agents.	☐		☒	
5.	Unable to follow all required study procedures for the whole period of the study.	☐		☒	
6.	Acute febrile illness or acute infectious disease.	☐		☒	
7.	Acute or chronic, clinically significant pulmonary, endocrine, autoimmune, psychiatric, cardiovascular, hepatic or renal functional abnormality, which in the opinion of the investigator might interfere with the study objectives.	☐		☒	
8.	History of a previous severe allergic reaction.	☐		☒	

9.	History of thrombocytopenia or known bleeding disorders.	☐	☒
10.	History or current use of drugs of abuse or heavy alcohol consumption.	☐	☒
11.	Received any other vaccines within 3 month prior to enrollment.	☐	☒
12.	History of serious and / or severe infections such as Hepatitis C virus (HCV), hepatitis Bvirus (HBV) infections, tuberculosis.	☐	☒
13.	Simultaneous participation in other clinical trials, previous participation in other clinical trials within 3 months before entering into the trial.	☐	☒
14.	History of untreated dog bites.	☐	☒

If Subject has received exceptions/waivers,
please provide description or waiver or any Comment _____

INCLUSION/EXCLUSION CRITERIA REVIEW

Has the Subject Eligible for randomization?	☒ Yes ☐ No
If No, please specify the inclusion / exclusion criteria numbers that were not met	
Inclusion Criteria number	_____
Exclusion criteria number	_____
If Subject has received exceptions/waivers, please provide description or waiver or any	_____

RANDOMIZATION:

Was the subject Randomized as per randomization plan? ☒ Yes ☐ No

If *Yes, provide the Date of Randomization: 08 - DEC - 2017

Subject number assigned: E P K - 0 0 1

Kit number: C 0 1

Treatment Arm ☒ **A: RABIMABs + Vaxirab N**

☐ **B: Rabies Immuno globulin (Imogam®) + Vaxirab N**

IMP ADMINISTRATION	
Date of study drug administration:	08 - DEC - 2017
Time of study drug administration:	11 : 20
Treatment Administered	☒A: RABIMABs + Vaxirab N ☐B: Rabies Immunoglobulin (Imogam®) +Vaxirab N
Total study drug administered?	10.4 ml 10 ml of rabimabs was taken from vial 1 and 0.4 ml taken from vial 2.
Was Study drug administered directly in the surround area of the wounds by dog bite?	☒Yes ☐No
Was Study drug administered intramuscularly in different part of the body?	☒Yes* ☐No
If Yes*, select site(s) of injection	☐Left Deltoid ☐Right Deltoid ☐Left Gluteal ☐Right Gluteal ☒Left Anterolateral thigh ☒Right Anterolateral thigh
Site of deltoid muscle (Vaxirab N)	☒Right ☐Left
Subject kept under observation up to 30 minutes after administration of assigned treatment.	☒Yes ☐No
Recorded by (sign and date):	08/12/17

LOCAL AND SYSTEMIC REACTION	
Has subject experienced any ☐ Local or ☐Systemic reaction?	☐Yes*☒No
If Yes*, please specify	☐Indurations ☐Redness ☐Pain ☐Fever ☐Swelling ☐Others
Comments (If Other, specify):	8/12/17 8/12/17

ADVERSE EVENT AND/ CONCOMITANT MEDIACTION ASSESSMENT	
Has the subject experienced any new adverse event in this visit?	☐Yes ☒No
Has the subject taken any new medication in this visit?	☐Yes ☒No

Comments:
0.4 ml extra Rabimabs was taken from extra bulk IP provided during shipment
Lab samples for Safety, ADA & RVNA has been processed as per protocol requirement.
08.12.17

PI or/ Designee Sign and Date: 8/12/17 11/12/17