**FORM SUBMISSION SCHEDULE FOR HIV-CORE VOLUNTEERS with Corresponding Days and Visit numbers**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Procedure/Study Week** | **Screen** | **0** | **1** | **24** | **4** | **5** | **6** | **8** | **12** | **16** | **30** | **44** | **483** |
| **Study day** | **-28** | **0** | **7** | **14** | **28** | **35** | **42** | **56** | **84** | **112** | **210** | **308** | **336** |
| **Visit Windows (Days)** | **(≤-28)** | **0** | **+3** | **+3** | **+3** | **+3** | **+3** | **+3** | **+7** | **+ 7** | **+ 7** | **+ 7** | **+ 7** |
| **Visit\*\*\*** | **01** | **02** | **02A** | **03** | **04** | **04A** | **05** | **06** | **07** | **08** | **09** | **10** | **11** |
| Informed consent | X |  |  |  |  |  |  |  |  |  |  |  |  |
| Eligibility Checklist (EG6) | X |  |  |  |  |  |  |  |  |  |  |  |  |
| Enrollment (ENR)24 |  | X |  |  |  |  |  |  |  |  |  |  |  |
| Randomization (RAN) |  | X |  |  |  |  |  |  |  |  |  |  |  |
| IP administration (IPA) |  | X |  |  | X |  |  |  |  |  |  |  |  |
| HIV-1 Risk Assessment (RA3) | X7,16 | X7,16 |  |  | X7,16 |  |  | X7,16 | X16 | X7,16 | X7,16 | X7,16 | X7,16 |
| Previous Conditions (HST) | X |  |  |  |  |  |  |  |  |  |  |  |  |
| Medical History (HX2) | X12 | X13 | X13 | X13 | X13 | X13 | X13 | X13 | X13 | X13 | X13 | X13 | X13 |
| Physical Exam (PXV) | X9,10,11,19 | X9,18,19 | X8,18,19 |  | X9,18,19 | X8,18,19 | X8,19 | X8,19 | X8,19 | X8,19 | X8,19 | X8,19 | X9,10,19 |
| Adverse Events (AD2) |  | X14,15 | X14,15 | X14,15 | X14,15 | X14,15 | X14,15 | X14,15 | X15 | X15 | X15 | X15 | X15 |
| Concomitant Medications (MED) | X | X | X | X | X | X | X | X |  |  |  |  |  |
| Reactogenicity Log1 (RXA) |  | X2 | X17 |  | X2 | X17 |  |  |  |  |  |  |  |
| Urinalysis (URI) | X |  |  |  |  |  |  | X |  |  |  | X |  |
| Haematology (HEM) | X | X | X |  | X | X |  | X |  |  | X |  | X |
| Chemistry (CHM) | X | X | X |  | X | X |  | X |  |  |  |  |  |
| HIV Virology/Serology (HV2) | X | X |  |  | X |  |  | X |  | X | X | X | X |
| Pregnancy Report (PR2) |  | X21 | X21 | X21 | X21 | X21 | X21 | X21 | X21 | X21 | X21 | X21 | X21 |
| Child Follow-up (CFF) |  | X21 | X21 | X21 | X21 | X21 | X21 | X21 | X21 | X21 | X21 | X21 | X21 |
| Miscellaneous Tests (MT2) | X20,22,23 | X20 |  |  | X20 |  |  | X20, 23 |  | X20, 23 | X 23 |  | X20, 23 |
| Sample Summary Form (LAB) 5 | X | X6 | X |  | X | X | X | X |  | X | X | X | X |
| Deviation report (SWD) | X21 | X21 | X21 | X21 | X21 | X21 | X21 | X21 | X21 | X21 | X21 | X21 | X21 |
| Visit/Contact Documentation – 01 (VS2) | X |  |  |  |  |  |  |  |  |  |  |  |  |
| Visit/Contact Documentation - IPA (VS3) |  | X |  |  |  |  |  |  |  |  |  |  |  |
| Visit/Contact Documentation – Follow-up (VS4) |  |  | X | X | X | X | X | X | X | X | X | X |  |
| Social Impact Assessment (SI2) |  |  |  |  |  |  |  |  |  |  |  |  | X |
| Volunteer Status Form (ST3) |  | X | X | X | X | X | X | X | X | X | X | X | X |
| 1 Reactogenicity will be collected from Day 0 to Day 7 after each vaccination  2 Collect at baseline and at least 30 min post vaccination  3 Early Termination (ET): Procedures to be performed at ET are the same as the Week 48 visit procedures  4 Visit can be conducted by phone. The visit may also be conducted in the clinic.  5 Faecal sample collection is optional  6 Faecal sample should be collected before administration of the first vaccine dose at enrolment.  7 HIV Risk Assessment, HIV Risk reduction counselling and HIV Test Counselling all done.  8 Symptom directed physical exam  9 General Physical exam at screening and before each vaccination  10 Volunteer weight recorded  11 Volunteer height recorded  12 Comprehensive medical history recorded  13 Interim medical history recorded  14 Non serious AE’s recorded  15 Serious AE’s recorded from first vaccination throughout, to the end of the study.  16 Family Planning counselling done on site or a family planning clinic.  17 Review of Reactogenicity event and Memory Aid by the Volunteer and study clinician  18 Cervical and Axillary lymph nodes assessed  19 Vital signs measured. Should also be measured at baseline and at least 30 minutes post vaccination  20 Urine pregnancy test must be carried at the specified time points  21 Form completed if required.  22 Hepatitis B Antigen test and Hepatitis C (HCV Antibodies) test carried out only during screening  23 Syphilis, Chlamydia trachomatis and Neisseria gonorrhoeae tests carried out  24 Eligibility Confirmation prior to enrolment  \*\*\* Visit numbers as listed on the Forms Submission Schedule are to be used on the source documents and lab samples. | | | | | | | | | | | | | |