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### 1.3. Schedule of Activities

The SoA table provides an overview of the protocol visits and procedures. Refer to the STUDY ASSESSMENTS AND PROCEDURES section of the protocol for detailed information on each procedure and assessment required for compliance with the protocol.

The investigator may schedule visits (unplanned visits) in addition to those listed in the SoA table, in order to conduct evaluations or assessments required to protect the well-being of the participant.

**Table 1. Schedule of Activities**

| **Visit Identifier** | **1** | **2** | **3** | **Notes** |
|---|---|---|---|---|
| **Visit Window** | **Day 1** | **28 to 35 Days After Visit 1** | **175 to 189 Days After Visit 1** | **Day 1 = Day of Vaccination** |
| **Visit Description** | **Vaccination** | **4-Week Follow-Up Visit** | **6-Month Follow-Up Visit** | |
| **Visit Type/Location** | **Site** | **Site** | **Site** | |
| Obtain informed consent | X | | | • Informed consent should be obtained prior to undergoing any study-specific procedures.<br>• See Section 10.1.3 for additional information. |
| Assign participant number | X | | | |
| Obtain demography and medical history data | X | | | |
| Perform clinical assessment, including oral temperature and seated blood pressure | X | | | Including, if indicated, a physical examination. |
| Measure height and weight | X | | | See Section 8.3.1 for additional information. |
| Collect nonstudy vaccine information, including COVID-19 and influenza vaccine information | X | X | X | See Section 6.9.1 for additional information. |
| Perform urine pregnancy test on WOCBP | X | | | See Section 8.3.6 for additional information. |

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## Table 1. Schedule of Activities

| Visit Identifier | 1 | 2 | 3 | Notes |
|---|---|---|---|---|
| **Visit Window** | **Day 1** | **28 to 35 Days After Visit 1** | **175 to 189 Days After Visit 1** | **Day 1 = Day of Vaccination** |
| **Visit Description** | **Vaccination** | **4-Week Follow-Up Visit** | **6-Month Follow-Up Visit** | |
| **Visit Type/Location** | **Site** | **Site** | **Site** | |
| Confirm use of contraceptives (if appropriate) | X | X | | See Section 5.3.1 for additional information. |
| Confirm eligibility | X | | | See Section 5 for additional information. |
| Review temporary delay criteria | X | | | See Section 5.5 for additional information. |
| Obtain randomization number and study intervention allocation | X | | | At registration, the participant enrollment number and dose-level allocation are assigned. |
| Collect blood sample for immunogenicity assessment | ~20 mL | ~20 mL | ~20 mL | • See Section 8.2 for additional information.<br>• For laboratory collection volumes, see the laboratory manual. |
| Administer study intervention | X | | | |
| Postvaccination observation (at least 30 minutes) and assessment of immediate events | X | | | |
| Explain participant communication methods (including for reactogenicity e-diary completion), assist the participant with downloading the application, or issue provisioned device, if required | X | | | See Section 8.3.4 for additional information. |
| Provide/ensure the participant has a thermometer and measuring device | X | | | |
| Review reactogenicity e-diary data (daily review is optimal during the active reactogenicity e-diary period [Days 1 through 7]) | ◄ | ► | | |

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## Table 1. Schedule of Activities

| Visit Identifier | 1 | 2 | 3 | Notes |
|---|---|---|---|---|
| **Visit Window** | **Day 1** | **28 to 35 Days After Visit 1** | **175 to 189 Days After Visit 1** | **Day 1 = Day of Vaccination** |
| **Visit Description** | **Vaccination** | **4-Week Follow-Up Visit** | **6-Month Follow-Up Visit** | |
| **Visit Type/Location** | **Site** | **Site** | **Site** | |
| Site reviews e-diary data with participant follow-up until ongoing symptom/medication resolution, if applicable | | X | X | Review the participant's e-diary data and record assessment in the CRF. Assess compliance, and any medically attended events (including hospitalizations). For symptoms still ongoing, continue to follow up until resolution, and document and record stop dates in the CRF. |
| Collect reactogenicity e-diary medication use | | X | | |
| Collect AEs and SAEs as appropriate | X | X | X | • See Section 8.4 for additional information.<br>• AEs are collected from the completion of informed consent through Visit 2. SAEs are collected from the completion of informed consent through the end of study participation. Additionally, any AEs occurring up to 48 hours after a blood draw must be recorded. |
| Collect e-diary or assist the participant with deleting the application | | X | | |