|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Participant Age | |  | |  | | | | | | | | | | | | | | | | | |
| **Adverse Event** (See codes below) | **If other, specify** | | **Date of administration of PZQ**  DD/MMM/YYYY | | **Date of administration of vaccine**  DD/MMM/YYYY  **And time of administration of vaccine(24hrs)** | **Start Date**  DD/MMM/YYYY | **Stop Date**  DD/MMM/YYYY | **Outcome**  1=Recovered  2=Recovered with sequelae  3=Continuing  4=Patient Died  5=Change in AE  6=unknown | **Severity**  0=None  1=Mild  2=Moderate  3=Severe | **Plausible relationship to Study Drug/Vaccine**  0=No relationship  1=Unlikely  2=Possible  3=Probable  4=Definite | **If there is a plausible relationship (Yes),** please specify the Drug/Vaccine (tick all that apply) | **Action taken with Adverse event**  1=None  2=Given Treatment  If treated, specify drug given | **Drug given**  1.Cetirizine  2=Piriton  3=ORS  4=Paracetamol  5=IV fluids  6=Prednisolon  7=Other, Specify | **Specify drug given** | **Withdrawn from study due to AE?** | | | **Serious AE (SAE)?**  **If yes, complete SAE form** | | |
|  |  | | / / | | / / |  |  |  |  |  | PZQ  BCG  Yellow fever  Td  HPV  Oral Typhoid |  |  |  |  |  |  |  |  |  |
| / / | / / |  |  | Yes |  |  | Yes |
|  |  |  |  |  |  |  |  |
|  |  |  |  | No |  |  | No |
|  |  |  |  |  |  |  |  |  |
|  |  | | / / | | / / |  |  |  |  |  | PZQ  BCG  Yellow fever  Td  HPV  Oral Typhoid |  |  |  |  |  |  |  |  |  |
| / / | / / |  |  | Yes |  |  | Yes |
|  |  |  |  |  |  |  |  |
|  |  |  |  | No |  |  | No |
|  |  |  |  |  |  |  |  |  |
|  |  | | / / | | / / |  |  |  |  |  | PZQ  BCG  Yellow fever  Td  HPV  Oral Typhoid |  |  |  |  |  |  |  |  |  |
| / / | / / |  |  | Yes |  |  | Yes |
|  |  |  |  |  |  |  |  |
|  |  |  |  | No |  |  | No |
|  |  |  |  |  |  |  |  |  |

Codes for AEs

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. Abdominal pains | 2. Dizziness | 3. Diarrhoea | 4. Diarrhoea with blood | 5. Vomiting | 6. Skin Rash | 7. Swelling |
| 8. Tenderness or pain at injection site | 9. Swelling at injection site | 10. Nausea | 11. Fever | 12. Headache | 13. Other (Specify) |  |

An SAE is an AE that results in any of the following outcomes, whether or not considered related to the study intervention.

* Death
* Life-threatening event (i.e., the participant was, in the view of the Investigator, at immediate risk of death from the event that occurred).
* Persistent or significant disability or incapacity (i.e., substantial disruption of one’s ability to carry out normal life functions).
* Hospitalisation, regardless of length of stay, even if it is a precautionary measure for continued observation. Hospitalisation (including inpatient or outpatient hospitalisation for an elective procedure) for a pre-existing condition that has not worsened unexpectedly does not constitute a serious AE.
* An important medical event (that may not cause death, be life threatening, or require hospitalisation) that may, based upon appropriate medical judgment, jeopardise the participant and/or require medical or surgical intervention to prevent one of the outcomes listed above. Examples of such medical events include allergic reaction requiring intensive treatment in an emergency room or clinic, blood dyscrasias, or convulsions that do not result in inpatient hospitalisation.
* Congenital anomaly or birth defect.

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| **Guidelines for assessing the relationship of vaccine administration to an SAE** | | |
| 0 | No Relationship | No temporal relationship to study intervention *and*  Alternate aetiology (clinical state, environmental or other interventions) *and*  Does not follow known pattern of response to study product |
| 1 | Unlikely | Unlikely temporal relationship to study product *and*  Alternate aetiology likely (clinical state, environmental or other interventions) *and*  Does not follow known typical or plausible pattern of response to study product. |
| 2 | Possible | Reasonable temporal relationship to study product; *or*  Event not readily produced by clinical state, environmental or other interventions; *or*  Similar pattern of response to that seen with other vaccines |
| 3 | Probable | Reasonable temporal relationship to study product; *and*  Event not readily produced by clinical state, environment, or other interventions *or*  Known pattern of response seen with other vaccines |
| 4 | Definite | Reasonable temporal relationship to study product; *and*  Event not readily produced by clinical state, environment, or other interventions; *and*  Known pattern of response seen with other vaccines |

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| **Severity grading criteria for local adverse events** | | |
| **Adverse Event** | **Grade** | **Intensity** |
| Pain at injection site | 1 | Pain that is easily tolerated |
|  | 2 | Pain that interferes with daily activity |
|  | 3 | Pain that prevents daily activity |
| Erythema at injection site\* | 1 | >3 - ≤50 mm |
|  | 2 | >50 - ≤100 mm |
|  | 3 | >100 mm |
| Swelling at injection site | 1 | >1 - ≤20 mm |
|  | 2 | >20 - ≤50 mm |
|  | 3 | >50 mm |
| \*erythema ≤3mm is an expected consequence of skin puncture and will therefore not be considered an adverse event | | |

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| --- | --- | --- | --- |
| **Severity grading criteria for physical observations** [appropriate adjustments will be made for age, gender and height percentiles] | | | |
|  | **Grade 1**  **(mild)** | **Grade 2**  **(moderate)** | **Grade 3**  **(severe)** |
| Fever | 37.6°C - 38.0°C | 38.1°C – 39.0°C | >39.0°C |
| Tachycardia (bpm)\* | 101 - 115 | 116 – 130 | >130 |
| Bradycardia (bpm)\*\* | 50 – 54 | 40 – 49 | <40 |
| Systolic hypertension (mmHg) | 141 - 159 | 160 – 179 | ≥180 |
| Diastolic hypertension (mmHg) | 91 - 99 | 100 – 109 | ≥110 |
| Systolic hypotension (mmHg)\*\*\* | 85 - 89 | 80 – 84 | <80 |
| \*Taken after ≥10 minutes at rest; \*\*When resting heart rate is between 60 – 100 beats per minute. Use clinical judgement when characterising bradycardia among some healthy participant populations, for example, conditioned athletes; \*\*\*Only if symptomatic (e.g. dizzy/ light-headed) | | | |

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| --- | --- |
| **Severity grading criteria for respiratory and systemic AEs** | |
| **GRADE 0** | None |
| **GRADE 1** | Mild: Transient or mild discomfort (< 48 hours); no medical intervention/therapy required |
| **GRADE 2** | Moderate: Mild to moderate limitation in activity – some assistance may be needed; no or minimal medical intervention/therapy required |
| **GRADE 3** | Severe: Marked limitation in activity, some assistance usually required; medical intervention/therapy required, hospitalisation possible |