**Adverse Event Coding Reference Sheet**

**[Protocol Number/Study]**

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| **Item** | **Code** | **Description** |
| **Stage of study** | 1 | Pre commencement |
| 2 | Baseline |
| 3 | Intervention days X-XX/ period |
| 4 | Follow-up |
| 5 | Post study |
| **System Classification** | 1 | Blood and Lymphatic |
| 2 | Cardiac disorders |
| 3 | Congenital, familial and genetic disorders |
| 4 | Ear and labyrinth disorders |
| 5 | Endocrine disorders |
| 6 | Eye disorders |
| 7 | Gastrointestinal disorders |
| 8 | General disorders and administration site conditions |
| 9 | Hepatobiliary disorders |
| 10 | Immune system disorders |
| 11 | Infections and Infestations |
| 12 | Injury, poisoning and procedural complications |
| 13 | Investigations |
| 14 | Metabolism and nutrition disorders |
| 15 | Musculoskeletal disorders |
| 16 | Neoplasms benign, malignant and unspecified (incl cysts and polyps) |
| 17 | Nervous system disorders |
| 18 | Pregnancy, puerperium and perinatal conditions |
| 19 | Psychiatric disorders |
| 20 | Renal and urinary disorders |
| 21 | Reproductive system and breast disorders |
| 22 | Respiratory, thoracic and mediastinal disorders |
| 23 | Skin and subcutaneous tissue disorders |
| 24 | Social disturbances |
| 25 | Surgical and medical procedures |
| 26 | Vascular disorders |
| **Adverse event** | Text | **In accordance with CTCAE terminology****(Refer to NCI criteria)** |
| **Start date of event** | dd/mm/yyyy | The date the event (or change of grade) started, first documented or first reported, whichever is earliest |

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| **Grade** | 1 | Grade 1: Mild; asymptomatic or mild, intervention not indicated |
| 2 | Grade 2: Moderate; minimal local or non-invasive intervention indicated |
| 3 | Grade 3: Severe of medically significant but not immediately life threatening |
| 4 | Grade 4: Life threatening consequences; urgent intervention indicated |
| 5 | Grade 5: Death related to AE |
| 99 | Unable to be graded |
| **Serious**\*Complete SAE report CRF (Template 40) and send to the ITCC within 24 hours of becoming aware of the event. | 1 | Yes\* |
| 2 | No |
| **AE of Special Interest**(refer to AE symptoms of interest guide) | 1 | Yes |
| 2 | No |
| **Relationship to study drug** | 1 | Unrelated |
| 2 | Unlikely |
| 3 | Possible |
| 4 | Probably |
| 5 | Definite |
| 99 | Not possible |
| **Assessment of cause** | 1 | Underlying study disease |
| 2 | Other underlying disease |
| 3 | Concomitant medication |
| 4 | Other |
| **Action Taken** | 1 | None |
| 2 | Study drug discontinued and no other treatment |
| 3 | Study drug discontinued and other treatment |
| 4 | Remedial drug therapy |
| 5 | Hospitalisation (and SAE) |
| 6 | Non drug treatment |
| 7 | Not able to be determined |
| 8 | Not applicable |
| 9 | Other action |
| **Outcome** | 1 | Resolved |
| 2 | Resolved with sequelae |
| 3 | Change in grade |
| 4 | Ongoing at end of study |
| 5 | Death |
| 6 | Unknown |
| **Date of Outcome** | dd/mm/yyyy | If the outcome is ‘ongoing at end of study’ or ‘unknown’, this is the date of the last study visit/contact.If outcome is ‘death’, enter the ‘date of death’. |