

# MAY2016-07-01 - Adverse Events Data Dictionary

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## Document Summary

| Property          | Value                                           |
|-------------------|-------------------------------------------------|
| Document Title    | MAY2016-07-01 - Adverse Events: Data Dictionary |
| Date Created      | 08/11/2025                                      |
| Sections          | 3                                               |
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## MAY2016-07-01 - Adverse Events: Data Dictionary

### Section 1: Identifiers

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| Class         | Variable       | Label                  | Description | Format Text |
|---------------|----------------|------------------------|-------------|-------------|
| 01. Principal | <b>subject</b> | Participant Identifier |             | Char        |

## Section 2: Study-wide

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| Class         | Variable      | Label         | Description | Format Text |
|---------------|---------------|---------------|-------------|-------------|
| 01. Principal | <b>ae_arm</b> | Treatment Arm |             | Numeric     |

## Section 3: Adverse Events

| Class         | Variable               | Label                                  | Description | Format Text                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|---------------|------------------------|----------------------------------------|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 01. Principal | <b>ae_attribute</b>    | AE Attribution                         |             | 1="Unrelated"<br>2="Unlikely"<br>3="Possible"<br>4="Probable"<br>5="Definite"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 01. Principal | <b>ae_course</b>       | Course                                 |             | Numeric                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 01. Principal | <b>ae_ctcae</b>        | CTCAE Term                             |             | Char                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 01. Principal | <b>ae_ctcae_v4_0</b>   | CTCAE V4.0                             |             | Numeric                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 01. Principal | <b>ae_grade</b>        | Grade                                  |             | Numeric                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 01. Principal | <b>ae_meddra_v12</b>   | MedDRA Adverse Event Code (CTCAE V4.0) |             | Numeric                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 01. Principal | <b>ae_off_study_dt</b> | Off Study Date                         |             | SAS Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 01. Principal | <b>ae_reported</b>     | Reported As SAE                        |             | 0="No"<br>1="Yes"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 01. Principal | <b>ae_reported_dt</b>  | Adverse Event Reported Date            |             | SAS Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 01. Principal | <b>ae_system_organ</b> | MedDRA System Organ Class (SOC)        |             | 1="Blood And Lymphatic System Disorders"<br>2="Cardiac Disorders"<br>4="Ear And Labyrinth Disorders"<br>6="Eye Disorders"<br>7="Gastrointestinal Disorders"<br>8="General Disorders And Administration Site Conditions"<br>10="Immune System Disorders"<br>11="Infections And Infestations"<br>12="Injury, Poisoning, And Procedural Complications"<br>13="Investigations"<br>14="Metabolism And Nutrition Disorders"<br>15="Musculoskeletal And Connective Tissue Disorders"<br>17="Nervous System Disorders"<br>19="Psychiatric Disorders"<br>20="Renal And Urinary Disorders,"<br>21="Reproductive System And Breast Disorders"<br>22="Respiratory, Thoracic, And Mediastinal Disorders"<br>23="Skin And Subcutaneous Tissue Disorders"<br>26="Vascular Disorders" |