**Adverse Event**

| **Data field** | **Description** | **Mandatory** | **Type** |
| --- | --- | --- | --- |
| Study identifier | The study identifier | Y | Text |
| Study part identifier | The study part identifier | Y | Text |
| Subject identifier | The subject identifier | Y | Text |
| AE Term | The term used to describe type of the adverse event | N | Text |
| AE Start Date | The start date of the event | Y | Date/Time |
| AE End Date | The end date of the event | N | Date/Time |
| Serious AE (yes/no) | Whether the AE was flagged as serious (Yes/No) | N | Text |
| Reasonable Possibility AE Caused by Investigational Product (yes/no) | Whether the AE was probably caused by Investigational Product | N | Text |
| Maximum severity grade | The max severity the AE achieved for the period specified (either AE CTC grade or AE Intensity grade can be used) | Y | Text |
| AE Number | The number assigned to the associated AE record | N | Number |
| Starting severity grade for AE | Starting severity grade for AE (either AE CTC grade or AE Intensity grade can be used) | N | Text |
| AE severity grade changes | Changes of AE severity grade over time (either AE CTC grade or AE Intensity grade can be used). If multiple severity grade columns are provided, these should be entered in the order that they occurred, separated by commas, corresponding to the dates provided in ‘AE severity change dates’ column. Note that aggregation function must be selected | N | Text |
| AE severity change dates | Dates of AE severity grade changes. If multiple date columns are provided, these should be entered in the order that they occurred, separated by commas, corresponding to the severity values provided in ‘AE severity grade changes’ column. Note that aggregation function must be selected | N | Date/Time |
| MEDDRA Version | The MEDDRA Version used to code the AE | N | Text |
| MEDDRA Preferred term | The MedDRA preferred term assigned to the AE | Y | Text |
| MEDDRA Higher-Level Term | The MedDRA Higher-Level Term for the AE | N | Text |
| MEDDRA Low-Level Term | The MedDRA Low-Level Term for the AE | N | Text |
| MEDDRA System Organ Class | The MedDRA System Organ Class of experienced AE | N | Text |
| Action taken | What action was taken due to the AE | N | Text |
| Investigational drug names | Names of the investigational drug | N | Text |
| Additional drug names | Names of the additional drug | N | Text |
| Initial action taken for investigational drugs | What action was taken due to the AE (investigational drugs) | N | Text |
| Initial action taken for additional drugs | What action was taken due to the AE (additional drugs) | N | Text |
| Action taken due to severity grade changes for investigational drugs | What action was taken due to severity grade changes (investigational drugs) | N | Text |
| Action taken due to severity grade changes for additional drugs | What action was taken due to severity grade changes (additional drugs) | N | Text |
| Causality for investigational drugs | Whether it is thought the AE is caused by the investigational drug (Yes/No) | N | Text |
| Causality for additional drugs | Whether it is thought the AE is caused by the additional drugs (Yes/No) | N | Text |
| AE Outcome | **Current state of the AE (e.g., resolved, recovering etc.)** | N | Text |
| Dose Limiting Toxicity | Whether the AE represents a level of toxicity that causes dose to be limited, reduced or stopped. (Yes/No) | N | Text |
| Time Point For Dose Limiting Toxicity | Description of the time point at which the AE reached a dose limiting toxicity (e.g. cycle number, visit number, date etc.) | N | Date/Time |
| Immune-mediated AE | Whether the AE is driven by immune system imbalance (Yes/No) | N | Text |
| Infusion Reaction AE | Whether the AE relates to the administration of drug via IV infusion (Yes/No) | N | Text |
| AE Required Treatment | Whether AE required treatment (Yes/No) | N | Text |
| AE Caused Subject Withdrawal | Whether AE caused subject withdrawal (Yes/No) | N | Text |
| Suspected Endpoint | Suspected clinical endpoint | N | Text |
| Suspected Endpoint Category | A category of suspected clinical endpoint | N | Text |
| AE of Special Interest | A custom grouping of AE terms that may have been mapped specifically for the given study or set of studies | N | Text |
| Comment | Comment | N | Text |