DATE CREATED: Jun28,2025
Number of Observations: 181
Number of Variables: 30

| **FileName** | **Variable\_label** | **Variable\_Name** | **Category** | **N\_\_Percent** | **Mean\_\_SD** | **Median\_Q1\_Q3** | **Range** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| review | Blind\_id | Blind\_id |  | 71(100) |  |  |  |
| review | Blinded\_SiteID | Blinded\_SiteID |  | 181(100) |  |  |  |
| review | B3. Adverse Event term as reported by site | AETERM |  | 181(100) |  |  |  |
| review | C6. Provide a brief summary of your review of this event: | COMMENTS |  | 181(100) |  |  |  |
| review | Visit Name | VISNAME | Addable Pages | 181(100) |  |  |  |
| review | C1. Do you agree with the event name assigned by the site? | AETERMAGR | (Empty string) | 1(0.6) |  |  |  |
| review | C1. Do you agree with the event name assigned by the site? | AETERMAGR | No | 1(0.6) |  |  |  |
| review | C1. Do you agree with the event name assigned by the site? | AETERMAGR | Yes | 179(98.9) |  |  |  |
| review | C1a. If No, specify event name: | AETERMREV | (Empty string) | 180(99.4) |  |  |  |
| review | C1a. If No, specify event name: | AETERMREV | Headaches (typo in original) | 1(0.6) |  |  |  |
| review | C2. In your opinion, is this event expected (nature or severity is consistent with information in the protocol, consent form, or Investigator brochure)? | EXPECTED | (Empty string) | 1(0.6) |  |  |  |
| review | C2. In your opinion, is this event expected (nature or severity is consistent with information in the protocol, consent form, or Investigator brochure)? | EXPECTED | No | 123(68) |  |  |  |
| review | C2. In your opinion, is this event expected (nature or severity is consistent with information in the protocol, consent form, or Investigator brochure)? | EXPECTED | Yes | 57(31.5) |  |  |  |
| review | C3. In your opinion, what was the intensity/grade of this event? (select one): | SEVERITY | Grade 1 - Mild | 151(83.4) |  |  |  |
| review | C3. In your opinion, what was the intensity/grade of this event? (select one): | SEVERITY | Grade 2 - Moderate | 28(15.5) |  |  |  |
| review | C3. In your opinion, what was the intensity/grade of this event? (select one): | SEVERITY | Grade 3 - Severe | 1(0.6) |  |  |  |
| review | C3. In your opinion, what was the intensity/grade of this event? (select one): | SEVERITY | Grade 4 - Life-Threatening Or Disabling | 1(0.6) |  |  |  |
| review | C4. In your opinion, is this an SAE? | SAE | No | 180(99.4) |  |  |  |
| review | C4. In your opinion, is this an SAE? | SAE | Yes | 1(0.6) |  |  |  |
| review | C4a. Resulted in death | DEATH | (Empty string) | 180(99.4) |  |  |  |
| review | C4a. Resulted in death | DEATH | No | 1(0.6) |  |  |  |
| review | C4b. Immediate life-threatening event (immediate danger of death from event) | LIFE\_THREAT | (Empty string) | 180(99.4) |  |  |  |
| review | C4b. Immediate life-threatening event (immediate danger of death from event) | LIFE\_THREAT | Yes | 1(0.6) |  |  |  |
| review | C4c. Requires inpatient hospitalization or prolongation of existing hospitalization | HOSP | (Empty string) | 180(99.4) |  |  |  |
| review | C4c. Requires inpatient hospitalization or prolongation of existing hospitalization | HOSP | Yes | 1(0.6) |  |  |  |
| review | C4d. Results in persistent or significant incapability or substantial disruption of the ability to conduct normal life functions | LIFE\_FUNC | (Empty string) | 180(99.4) |  |  |  |
| review | C4d. Results in persistent or significant incapability or substantial disruption of the ability to conduct normal life functions | LIFE\_FUNC | No | 1(0.6) |  |  |  |
| review | C4e. Results in a congenital anomaly in the offspring of a participant | CONG\_ANOM | (Empty string) | 180(99.4) |  |  |  |
| review | C4e. Results in a congenital anomaly in the offspring of a participant | CONG\_ANOM | No | 1(0.6) |  |  |  |
| review | C4f. Important Medical Event: Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject’s health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria | IMPORT\_EVENT | (Empty string) | 180(99.4) |  |  |  |
| review | C4f. Important Medical Event: Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject’s health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria | IMPORT\_EVENT | No | 1(0.6) |  |  |  |
| review | C5. In your opinion, what was the relationship of the event to study drug? (select one): | CAUSALITY | Definitely Related | 1(0.6) |  |  |  |
| review | C5. In your opinion, what was the relationship of the event to study drug? (select one): | CAUSALITY | Not related | 92(50.8) |  |  |  |
| review | C5. In your opinion, what was the relationship of the event to study drug? (select one): | CAUSALITY | Possibly Related | 85(47) |  |  |  |
| review | C5. In your opinion, what was the relationship of the event to study drug? (select one): | CAUSALITY | Probably Related | 3(1.7) |  |  |  |
| review | LLT CODE | LLT\_CODE | 10019211 | 1(100) |  |  |  |
| review | LLT CODE | LLT\_CODE | <NA> | 180(NA) |  |  |  |
| review | LLT NAME | LLT\_NAME | (Empty string) | 180(99.4) |  |  |  |
| review | LLT NAME | LLT\_NAME | Headache | 1(0.6) |  |  |  |
| review | PT CODE | PT\_CODE | 10019211 | 1(100) |  |  |  |
| review | PT CODE | PT\_CODE | <NA> | 180(NA) |  |  |  |
| review | PT TERM | PT\_TERM | (Empty string) | 180(99.4) |  |  |  |
| review | PT TERM | PT\_TERM | Headache | 1(0.6) |  |  |  |
| review | HLT CODE | HLT\_CODE | 10019233 | 1(100) |  |  |  |
| review | HLT CODE | HLT\_CODE | <NA> | 180(NA) |  |  |  |
| review | HLT TERM | HLT\_TERM | (Empty string) | 180(99.4) |  |  |  |
| review | HLT TERM | HLT\_TERM | Headaches NEC | 1(0.6) |  |  |  |
| review | HLGT CODE | HLGT\_CODE | 10019231 | 1(100) |  |  |  |
| review | HLGT CODE | HLGT\_CODE | <NA> | 180(NA) |  |  |  |
| review | HLGT TERM | HLGT\_TERM | (Empty string) | 180(99.4) |  |  |  |
| review | HLGT TERM | HLGT\_TERM | Headaches | 1(0.6) |  |  |  |
| review | SOC CODE | SOC\_CODE | 10029205 | 1(100) |  |  |  |
| review | SOC CODE | SOC\_CODE | <NA> | 180(NA) |  |  |  |
| review | SOC TERM | SOC\_TERM | (Empty string) | 180(99.4) |  |  |  |
| review | SOC TERM | SOC\_TERM | Nervous system disorders | 1(0.6) |  |  |  |
| review | A1. Age at Date of review: | REVAge |  | 181(100) | 15.61(2.4) | 15.43(13.9,17.27) | 10.96,22.48 |
| review | B1. AE Number (from corresponding Adverse Event - Initial Report page) | AENUM |  | 180(99) | 3.86(3.6) | 2(1,5) | 1,19 |
| review | B2. Age at Date of onset | STAge |  | 148(82) | 14.89(2.2) | 14.58(13.23,16.72) | 10.11,20.51 |