DATE CREATED: Jun28,2025  
Number of Observations: 362  
Number of Variables: 8

| **FileName** | **Variable\_label** | **Variable\_Name** | **Category** | **N\_\_Percent** | **Mean\_\_SD** | **Median\_Q1\_Q3** | **Range** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| dv | Blind\_id | Blind\_id |  | 106(100) |  |  |  |
| dv | Blinded\_SiteID | Blinded\_SiteID |  | 362(100) |  |  |  |
| dv | A4. Provide a description of the specific deviation | DVDESC |  | 362(100) |  |  |  |
| dv | Visit Name | VISNAME | Addable Pages | 362(100) |  |  |  |
| dv | A2. Study visit associated with deviation | DVVISIT | 1 Month | 43(11.9) |  |  |  |
| dv | A2. Study visit associated with deviation | DVVISIT | 12 Month | 88(24.3) |  |  |  |
| dv | A2. Study visit associated with deviation | DVVISIT | 18 Month | 34(9.4) |  |  |  |
| dv | A2. Study visit associated with deviation | DVVISIT | 24 Month | 92(25.4) |  |  |  |
| dv | A2. Study visit associated with deviation | DVVISIT | 6 Month | 84(23.2) |  |  |  |
| dv | A2. Study visit associated with deviation | DVVISIT | 9 Month | 2(0.6) |  |  |  |
| dv | A2. Study visit associated with deviation | DVVISIT | Baseline | 13(3.6) |  |  |  |
| dv | A2. Study visit associated with deviation | DVVISIT | Screening | 6(1.7) |  |  |  |
| dv | A3. Please indicate the category of deviation | DVCAT | Clinical Assessment violation | 176(48.6) |  |  |  |
| dv | A3. Please indicate the category of deviation | DVCAT | Follow-up compliance | 89(24.6) |  |  |  |
| dv | A3. Please indicate the category of deviation | DVCAT | Lab value violation | 18(5) |  |  |  |
| dv | A3. Please indicate the category of deviation | DVCAT | Other | 64(17.7) |  |  |  |
| dv | A3. Please indicate the category of deviation | DVCAT | Randomization violation | 2(0.6) |  |  |  |
| dv | A3. Please indicate the category of deviation | DVCAT | Study medication compliance | 13(3.6) |  |  |  |
| dv | A5. Was this deviation reported to the IRB? | DVIRB | No | 319(88.1) |  |  |  |
| dv | A5. Was this deviation reported to the IRB? | DVIRB | Yes | 43(11.9) |  |  |  |
| dv | A1. Age at Date deviation occurred | DVAge |  | 362(100) | 15.17(2.5) | 14.7(13.28,17.16) | 10.11,21.14 |