DATE CREATED: Jun28,2025
Number of Observations: 25
Number of Variables: 9

| **FileName** | **Variable\_label** | **Variable\_Name** | **Category** | **N\_\_Percent** | **Mean\_\_SD** | **Median\_Q1\_Q3** | **Range** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| tdis | Blind\_id | Blind\_id |  | 15(100) |  |  |  |
| tdis | Blinded\_SiteID | Blinded\_SiteID |  | 25(100) |  |  |  |
| tdis | Visit Name | VISNAME | Study Drug Visits | 25(100) |  |  |  |
| tdis | A2. Reason for temporary Discontinuation of Study Drug <i>(select all that apply)</i> | REASON | (Empty string) | 1(4) |  |  |  |
| tdis | A2. Reason for temporary Discontinuation of Study Drug <i>(select all that apply)</i> | REASON | Increase In Alt To >= 200 For > 2 Weeks | 2(8) |  |  |  |
| tdis | A2. Reason for temporary Discontinuation of Study Drug <i>(select all that apply)</i> | REASON | Increase In Alt To >= 3 Times The Baseline For > 2 Weeks | 1(4) |  |  |  |
| tdis | A2. Reason for temporary Discontinuation of Study Drug <i>(select all that apply)</i> | REASON | Other Reason | 21(84) |  |  |  |
| tdis | A2a. If Other reason, please Specify | SPECIFY | (Empty string) | 4(16) |  |  |  |
| tdis | A2a. If Other reason, please Specify | SPECIFY | Current Drug Supply In Pharmacy Expires In October And Can No Longer Be Dispensed. The New Supply Of Drug Has Not Yet Been Delivered To Site. | 1(4) |  |  |  |
| tdis | A2a. If Other reason, please Specify | SPECIFY | Due to study drug expiration date site was not authorized to issue new bottles to participant until we get the new bottles. | 1(4) |  |  |  |
| tdis | A2a. If Other reason, please Specify | SPECIFY | Increase In Alt To >3 Times Comparing Within 5 Weeks | 1(4) |  |  |  |
| tdis | A2a. If Other reason, please Specify | SPECIFY | Participan did not have any more study drug. The study drug was restarted. | 1(4) |  |  |  |
| tdis | A2a. If Other reason, please Specify | SPECIFY | Participant chose to stopped taking the study intervention for about 2 months | 1(4) |  |  |  |
| tdis | A2a. If Other reason, please Specify | SPECIFY | Participant Decided To Stop The Study Medication Because He Forgot To Take It. He Said That They Attended Multiple Parties And He Just Forgot To Take It. | 1(4) |  |  |  |
| tdis | A2a. If Other reason, please Specify | SPECIFY | Participant Decided To Stop The Study Medication Due To Personal Preference, He Informed The Parent Of His Decision Until The Day Before The 12 Month Visit. Counseling Was Provided On Compliance. | 1(4) |  |  |  |
| tdis | A2a. If Other reason, please Specify | SPECIFY | Participant Developed Sore Throat And Subsequently Diagnosed With Hand-Foot-Mouth Disease So Parent Decided To Stop The Study Medication Because She Did Not Want The Child To Take It While He Was Sick | 1(4) |  |  |  |
| tdis | A2a. If Other reason, please Specify | SPECIFY | Participant Forgot | 1(4) |  |  |  |
| tdis | A2a. If Other reason, please Specify | SPECIFY | Participant Forgot To Take Study Intervention Due To Summer Time/Vacation. | 1(4) |  |  |  |
| tdis | A2a. If Other reason, please Specify | SPECIFY | Participant forgot to take the study drug during the summer. She said she forgot to take it for 24 days. | 1(4) |  |  |  |
| tdis | A2a. If Other reason, please Specify | SPECIFY | Participant Forgot To Take The Study Drug. | 2(8) |  |  |  |
| tdis | A2a. If Other reason, please Specify | SPECIFY | Participant forgot to take the study drug. He stopped taking the old study drug on this date, but forgot to opened the new study drug and didn't start taking it until 10 days later. | 1(4) |  |  |  |
| tdis | A2a. If Other reason, please Specify | SPECIFY | Participant forgot to take the study intervention for about 5 days, he does not remember the exact date. | 1(4) |  |  |  |
| tdis | A2a. If Other reason, please Specify | SPECIFY | Patient Had A Fractured Teeth Playing Softball | 1(4) |  |  |  |
| tdis | A2a. If Other reason, please Specify | SPECIFY | Patient Reports He Has Been More Forgetful With Study Medication. He Has Not Been Taking It For The Last 2 Months | 1(4) |  |  |  |
| tdis | A2a. If Other reason, please Specify | SPECIFY | Patient Stopped Meds Because She Forgot To Take Them. | 1(4) |  |  |  |
| tdis | A2a. If Other reason, please Specify | SPECIFY | Subject Reported At Last Visit Did Not Take While Working As A Camp Counselor | 1(4) |  |  |  |
| tdis | A2a. If Other reason, please Specify | SPECIFY | Subject Reported Vomiting | 1(4) |  |  |  |
| tdis | A2a. If Other reason, please Specify | SPECIFY | Subject Thought Drug Was Causing Stomach Pain, But Found It Was Unrelated Once They Started Med Again. | 1(4) |  |  |  |
| tdis | A3. AE ID Number (if applicable): | AESPID | 0 | 4(33.3) |  |  |  |
| tdis | A3. AE ID Number (if applicable): | AESPID | 1 | 5(41.7) |  |  |  |
| tdis | A3. AE ID Number (if applicable): | AESPID | 2 | 1(8.3) |  |  |  |
| tdis | A3. AE ID Number (if applicable): | AESPID | 3 | 1(8.3) |  |  |  |
| tdis | A3. AE ID Number (if applicable): | AESPID | 14 | 1(8.3) |  |  |  |
| tdis | A3. AE ID Number (if applicable): | AESPID | <NA> | 13(NA) |  |  |  |
| tdis | A4. Was the study drug restarted? | TDSTYN | (Empty string) | 1(4) |  |  |  |
| tdis | A4. Was the study drug restarted? | TDSTYN | No | 5(20) |  |  |  |
| tdis | A4. Was the study drug restarted? | TDSTYN | Yes | 19(76) |  |  |  |
| tdis | A1. Age at Date of temporary discontinuation of study drug | TDISAge |  | 24(96) | 15.27(2.2) | 15.34(13.76,16.95) | 11.4,19.61 |
| tdis | A4a. Age at Restart Date | TDSTAge |  | 19(76) | 14.95(2) | 15.3(13.69,16.4) | 11.49,17.99 |