Did the subject take any non-study AEDs during the study?  Yes *(Follow instructions below)*  No

Please record all non-study AEDs the participant/subject took while participating in the study. Enter each dose change on a new line.[[1]](#footnote-1)

Table for Recording Anti Epileptic Drug Log Data Details

| Name of AED | Generic or  Brand  Used? | Formulation  (e.x., extended release, liquid, sprinkle, etc.) | Dosing Schedule -Times of Administration  (00:00-24:00; 99:99=Unknown,  88:88=N/A) | Dose and Units | Route | Start Date  (m m/dd/yyyy)  Stop Date  (m m/dd/yyyy) | Ongoing? | If Applicable, Reason for Discontinuation  (Check all that apply) | Comments |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Data to be entered | Generic  Brand  Unknown | Data to be entered by site | :  :  :  :  N/A - taken PRN: Average frequency = times per month | Data to be entered by site | Data to be entered by site | Start:  //  Stop:  // | Yes  No | Idiosyncratic Side Effect(s), specify:  Dose Related Side Effect(s), specify:  Chronic Side Effects  Inadequate Seizure Control  Other, specify: | Data to be entered by site |
| Data to be entered | Generic  Brand  Unknown | Data to be entered by site | :  :  :  :  N/A - taken PRN: Average frequency = times per month | Data to be entered by site | Data to be entered by site | Start:  //  Stop:  // | Yes  No | Idiosyncratic Side Effect(s), specify:  Dose Related Side Effect(s), specify:  Chronic Side Effects  Inadequate Seizure Control  Other, specify: | Data to be entered by site |

## General Instructions

Changes to Non study AEDs should be captured during the study period. In some cases, the protocol may request that tracking of non-study AEDs begin prior to initiation of study medication. Collecting Anti Epileptic medications taken prior to the study in a defined time window (e.g. 30 days) may be important when there may be potential interactions with the study intervention.

Collecting AEDs taken during a study is important for safety reasons, and to determine whether outcome was altered by changes to medication. Some AEDs may interact with the study intervention and must not be taken during the study. If taken, it should be indicated as a protocol deviation. Some studies may prohibit changes to background AEDs during active intervention. Participants/Subjects or their caregivers should be asked to bring prescription and over-the-counter medications to follow-up visits so that the medications can be recorded on the case report form.

The Anti Epileptic Drug Log should be filled out at the baseline visit and every study visit/time point thereafter. The form may be modified so that a separate CRF is filled out at each study visit, rather than maintaining a running log. The following abbreviations are recommended to capture dose units:

* g = gram
* gr =grain
* gtt = drop
* mcg =microgram
* mcL = microliter
* mg = milligram
* mL = milliliter
* oz = ounce
* SPY = spray/squirt
* supp = suppository
* TBSP = tablespoon
* Sp = teaspoon
* OTH = other, specify
* UNK= Unknown

Studies that plan to submit their data to regulatory authorities are recommended to code their medication data using a standard terminology such as the WHO Drug dictionary.

1. All other medications (i.e., non AEDs) should be recorded on the Non Anti Epileptic Medication Log. [↑](#footnote-ref-1)