1. Did the participant/subject take any medications within (please specify) days prior study participation or during the study?

Yes  No (STOP)

If Yes, please complete the tables below for each concomitant medication. Include all prescription medications, vitamins, herbal supplements, and over the counter (OTCs).

Table 1: Recording Medications Taken by the Participant/Subject on **Regular Basis**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1Medication Name (Trade / generic  name) | 2Indication | 3Dose per  Administration | 4Units of  Dose | 5Frequency | 6Route | 7Start Date | End Date\* | 8Ongoing? |
|  |  |  |  |  |  |  |  | Yes  No  Unknown |
|  |  |  |  |  |  |  |  | Yes  No  Unknown |
|  |  |  |  |  |  |  |  | Yes  No  Unknown |

Table 2: Recording Medications Taken by the Participant/Subject on **As-Needed Basis**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1Medication Name (Trade / generic  name) | 2Indication | 3Dose per  Administration | 4Units of  Dose | 5Frequency | 6Route | 7Start Date | End Date\* | 8Ongoing? |
|  |  |  |  |  |  |  |  | Yes  No  Unknown |
|  |  |  |  |  |  |  |  | Yes  No  Unknown |
|  |  |  |  |  |  |  |  | Yes  No  Unknown |

|  |  |  |
| --- | --- | --- |
| Codelist: Please chose one and enter under the appropriate corresponding cell | | |
| **4Units of Dose** | **5Frequency** | **6Route** | |
| g = gram  gr = grain  gtt = drop  mcg = microgram  mcL = microliter  mg = milligram  mL = milliliter  oz = ounce  tbsp = tablespoon  tsp = teaspoon  U= unit  UNK = Unknown  OTH = Other, specify | BID = Twice daily  TID = Three times a day  QID = Four times a day  Q2H = Every 2 hours  Q4H = Every 4 hours  Q6H = Every 6 hours  Q8H = Every 8 hours  QAM = One dose in morning  QPM = One dose in evening  QD = Once daily  HS = At bedtime  PRN = As needed  OTH = Other  UNK = Unknown | INH = Inhaled (Respiratory)  IM = Intramuscular  ID= Intradermal  IV = Intravenous  NS = Nasal  PO = Oral (swallow)  SC = Subcutaneous  TOP = Topical  BUC = Buccal (towards back of mouth)  AU= Both ears (AD= right ear, AS=left ear)  PR= Rectal  SL = Sublingual (taken under tongue)  TD = Transdermal  SPY = spray/squirt  SUPP = Suppository, specify:  R (rectal suppository)  V (vaginal suppository)  U (urethral suppository)  RD= Rapid Dissolve  OTH = Other, specify:  UNK = Unknown | |

GENERAL INSTRUCTIONS

Collecting medications taken prior to the study in a defined time window (e.g., 30 days) is important when there may be potential interactions with the study intervention. The purpose of this form is to collect all medications besides study medications, including mediations used to treat headache or migraine within the time window. Thus, a potential participant/subject may need to stop a medication prior to starting the study intervention (washout period). Furthermore, the study exclusion criteria may identify drugs that cannot be taken during the study and so prior medications are identified to determine whether an individual may be eligible for the study.

Collecting concomitant medications taken during a study is also important for safety reasons. Some drugs may interact with the study intervention and must not be taken during the study. Additionally, there may be some drugs that are not known to interact with the study intervention and may be identified through an adverse event. It may be helpful to ask study participants/subjects or their caregivers to bring prescription and over-the-counter medications to follow-up visits so that the medications can be more easily and accurately recorded on the CRF.

The Concomitant Medications form should be filled out at the baseline visit and every study visit/time point thereafter. It is important to be very explicit and detailed when completing this form to ensure the relevant and accurate data is collected.

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.

## SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

* Did the participant/subject take any medications within days prior study participation or during the study? – No additional instructions
* Table 1 – Please complete this table for medication that the participant took on a regular basis.
* Table 2 – Please complete this table for medication that the participant took on an as-needed basis.
* Medication Name – Verbatim name (generic or trade name) of the medication, including vitamins and herbal supplements the participant/subject reports taking.
* Indication – Record the reason the participant/subject gives for taking the medication.
* Dose – Record the strength of the medication the participant/subject is taking.
* Units – Record the units of the medication the participant/subject is taking. The code list displays the most common dose unit options.
* Frequency – Record how often the medication is being taken. The code list displays the most common options.
* Route – Record the route of administration. The code list displays the most common options.
* Start Date – Record the day, month, and year the participant/subject started taking the medication. Start Date can be used to distinguish between prior medications and concomitant medications. This field should be completed to the best of the Investigator’s knowledge.
* End Date – Record the day, month, and year the participant/subject stopped taking the medication. Stop Date should be recorded if Ongoing? is answered No. Conversely, Stop Date should remain blank if Ongoing? is answered Yes. This field should be completed to the best of the Investigator’s knowledge.
* Ongoing – Answer Yes if the participant/subject is still taking the medication or No if the participant/subject has discontinued taking the medication.