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 / genericname) | 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 / genericname) | 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 = gramgr = graingtt = dropmcg = microgrammcL = microlitermg = milligrammL = milliliteroz = ouncetbsp = tablespoontsp = teaspoonU= unit UNK = UnknownOTH = Other, specify | BID = Twice dailyTID = Three times a dayQID = Four times a dayQ2H = Every 2 hours Q4H = Every 4 hoursQ6H = Every 6 hoursQ8H = Every 8 hoursQAM = One dose in morningQPM = One dose in eveningQD = Once dailyHS = At bedtimePRN = As neededOTH = OtherUNK = Unknown | INH = Inhaled (Respiratory)IM = IntramuscularID= IntradermalIV = IntravenousNS = Nasal PO = Oral (swallow)SC = SubcutaneousTOP = TopicalBUC = Buccal (towards back of mouth)AU= Both ears (AD= right ear, AS=left ear)PR= RectalSL = Sublingual (taken under tongue)TD = TransdermalSPY = spray/squirtSUPP = Suppository, specify:R (rectal suppository)V (vaginal suppository) U (urethral suppository)RD= Rapid DissolveOTH = 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.