This form is completed whenever rescue treatment (medication, device, other intervention) is administered.

1. Did the participant/subject receive any additional pain or headache medication(s) after the study drugs were administered?

[ ]  Yes [ ]  No (STOP) [ ]  Unknown (STOP)

If Yes, complete the table below indicating rescue medication(s) that the participant/subject received:

Table 1: Rescue Treatment Administered

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Rescue Treatment  | Time Rescue Drug Administered (24 hour clock)  | Time Study Drug Administered (24 hour clock) | 1Pain Severity(complete *one* of the following scales) | Dose Administered | 2Unit  | 3Route of Administration  |
|  |  |  | [ ]  0 [ ]  6[ ]  1 [ ]  7[ ]  2 [ ]  8[ ]  3 [ ]  9[ ]  4 [ ]  10[ ]  5 | [ ]  None[ ]  Mild[ ]  Moderate[ ]  Severe |  |  |  |
|  |  |  | [ ]  0 [ ]  6[ ]  1 [ ]  7[ ]  2 [ ]  8[ ]  3 [ ]  9[ ]  4 [ ]  10[ ]  5 | [ ]  None[ ]  Mild[ ]  Moderate[ ]  Severe |  |  |  |
|  |  |  | [ ]  0 [ ]  6[ ]  1 [ ]  7[ ]  2 [ ]  8[ ]  3 [ ]  9[ ]  4 [ ]  10[ ]  5 | [ ]  None[ ]  Mild[ ]  Moderate[ ]  Severe |  |  |  |

1Pain Severity Scale(s)- the pain severity scale used to document the pain intensity at the time of the rescue therapy, should be the SAME pain intensity scale used to document the primary outcome measure

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Codelist: Choose a value and enter it under the appropriate corresponding table cell.

|  |  |
| --- | --- |
| 2Units of Dose |  3Route of Administration |
| g = gramgr = graingtt = dropmcg = microgrammcL = microlitermg = milligrammL = milliliteroz = ouncetbsp = tablespoontsp = teaspoonU= unit UNK = UnknownOTH = Other, specify | INH = Inhaled (respiratory) SPY = spray/squirtIM = Intramuscular SUPP = Suppository, specify:ID= Intradermal R (rectal suppository)IV = Intravenous V (vaginal suppository) NS = Nasal U (urethral suppository)PO = Oral (swallow) RD= Rapid DissolveSC = Subcutaneous OTH = Other, specify:TOP = Topical UNK = UnknownPR= RectalBUC = Buccal (towards back of mouth)AU= Both ears (AD= right ear, AS=left ear)SL = Sublingual (taken under tongue)TD = Transdermal |
|  |  |

1. Were any rescue devices used in the treatment of headache or migraine?

[ ] Yes [ ] No

* 1. If yes, complete the following:
1. Device Name:
2. Date Started:
3. Date Ended:

## GENERAL INSTRUCTIONS

This form contains data elements that are collected when rescue medications are administered for headaches and migraines. The questions should be answered to the best of the participant’s/subjects ability. This information will be used to assist in the participant’s/subject’s care.

## SPECIFIC INSTRUCTIONS

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

* Did the patient receive any additional pain or headache medication after the study drugs were administered? – No additional instructions
	+ If Yes, complete the rescue medication(s) that the participant/subject received
		- NOTE: In a clinical trial, this CRF defines rescue medication as any medication given after primary treatment.
	+ Date/Time – Record the date/time according to the ISO 8601, the International Standard for the representation of dates and times ( [International Organization for Standardization Website](http://www.iso.org/iso/home.html)). The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.).
	+ Treatment Name – Verbatim name (generic or trade name) of the rescue medication or treatment the participant/subject has received.
	+ Time Rescue Drug Administered – Record time that rescue drug was administered in 24 hour format.
	+ Time Study Drug Administered – Record time that study drug was administered in 24 hour format.
	+ Pain Severity – Record headache pain severity at time of administering treatment by completing either the 0-10 scale or the “None, Mild, Moderate, Severe’ scale.
		- Note: that the pain severity scale used to document the pain intensity at the time of the rescue therapy, should be the SAME pain intensity scale used to document the primary outcome measure.
	+ Dose Administered – Record dose administered.
	+ Unit – Record unit of dose administered; refer to the codelist for a list of values.
	+ Route of Administration – Record route of administration; refer to the codelist for a list of values.