Instructions: For each day, please answer following questions. Please see instructions for more information. Research staff should define and inform participant of headache and migraine symptoms prior to filling out the calendar.

**Table 1: Sample Calendar**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Sunday | Monday | Tuesday | Wednesday | Thursday | Friday | Saturday |
| [[1]](#footnote-1) Date:  [[2]](#footnote-2) Headache Y N  [[3]](#footnote-3) Migraine Y N  [[4]](#footnote-4) Time Onset:  [[5]](#footnote-5) Time End:  [[6]](#footnote-6) Severity: | Date:  Headache Y N  Migraine Y N  Time Onset:  Time End:  Severity: | Date:  Headache Y N  Migraine Y N  Time Onset:  Time End:  Severity: | Date:  Headache Y N  Migraine Y N  Time Onset:  Time End:  Severity): | Date:  Headache Y N  Migraine Y N  Time Onset:  Time End:  Severity: | Date:  Headache Y N  Migraine Y N  Time Onset:  Time End:  Severity: | Date:  Headache Y N  Migraine Y N  Time Onset:  Time End:  Severity: |

## General Instructions

This CRF Module is recommended for all headache and migraine studies that need to collect headache occurrence data on a daily basis. The information provided in the diary should be completed and reviewed per the study requirements. If the participant/subject indicates presence of a headache or migraine on the diary, it is also recommended to complete the appropriate Headache Record CRF (Acute or Preventive) that captured additional detailed information regarding the headache/migraine. Use the comments section to provide any additional information that pertains to the headache or migraine.

## Specific Instructions

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

1 = Date – Record the date according to the ISO 8601, the International Standard for the representation of dates and times (([Click here for International Standard for Dates and Times](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.).

2, 3= Indicate if Headache or Migraine occurred – A migraine is defined as pain in the head that includes at least 2 or more of the following features (1. throbbing; 2. pain in front, side, top, or back of head; 3. moderate or severe pain; 4. Worsen with activity) AND 1 or more of the following 2 associated symptoms (1. nausea and/or vomiting; 2. light/sound sensitivity). If headache or migraine was not presented, please indicate no.

4,5 = Time – Record the start and end time according to the ISO 8601, the International Standard for the representation of dates and times (([Click here for International Standard for Dates and Times](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.).

6 = Severity – Indicate pain severity of current headache or migraine. Use either the 0-10 scale, or none, mild, moderate, severe. Please note that “0” indicates no pain and “10” indicates worst pain imaginable.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 0  No  pain | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10  worst pain  imaginable |

## Reference

Hershey AD, Powers S 2011. Amitriptyline and Topiramate in the Prevention of Childhood Migraine Study.

1. Date – indicate month, day, and year. [↑](#footnote-ref-1)
2. Headache – did participant experience a headache? [↑](#footnote-ref-2)
3. Migraine – did participant experience a migraine? [↑](#footnote-ref-3)
4. Time Onset/End – indicate what time headache/migraine started.

   5Time Onset/End – indicate what time headache/migraine ended.

   6Severity – indicate headache/migraine pain severity using the 0-10 scale or none, mild, moderate, severe. [↑](#footnote-ref-4)
5. [↑](#footnote-ref-5)
6. [↑](#footnote-ref-6)