*Instructions: This form should be completed by the participant for each day the participant/subject experienced a headache/migraine.*

1. Did you experience a headache today?  Yes  No
2. What time did your headache start?  (24 hour clock)  Woke up with this headache
3. What time did your headache end?  (24 hour clock)  Headache resolved after falling asleep
4. What acute pain medication(s), in addition to the study drug, did you take? (Choose all that apply)

Acetaminophen

Almotriptan

Aspirin

Dihydroergotamine (DHE)

Eletriptan

Ergotamine tartrate (ET)

Frovatriptan

Ibuprofen

Naproxen

Naratriptan

Rizatriptan

Sumatriptan

Zolmitriptan

Other, specify:

1. Describe the worst severity of your headache today? Complete **one** of the following pain severity scales:
2. Which word describes the severity of your headache?

None  Mild  Moderate  Severe  Very Severe (for cluster headaches)

1. Rate your overall worst pain for this headache on a scale of 0-10: (“0” = no pain & “10” = the worst pain):  0  1  2  3  4  5  6  7  8  9  10
2. Do any of the following describe your pain? (Choose all that apply)

Throbbing

Pounding

Stabbing

Constant

Sharp

Pressure

Pulsating with the heart beat

Squeezing

Other, specify:

1. Where is the location of your headache pain? (Choose one)

Right  Left  Bilateral (both sides)

1. Where is the location of your headache pain that hurts the most? (Choose all that apply)

Top

One Eye (specify,  left  right)

Around Eyes

Behind Eyes

Back

Neck

All over

Right Temple

Left Temple

Front

Other, specify:

1. Does sound aggravate or make your headache worse?  Yes  No
2. Does light aggravate or make your headache worse?  Yes  No
3. Does routine physical activity (e.g. walking, climbing stairs) aggravate or make your headache worse?  Yes  No
4. Optional - Did you have any symptoms that came before and warned that this headache was going to start?

Yes  No  Unknown

1. If premonitory symptoms (symptoms that come *before* headache), which of the following did you experience? (Choose all that apply)

Fatigue

 Difficulty concentrating

 Irritability

 Mood Changes

 Food Cravings

 Nausea

Yawning

 Neck stiffness / pain

 Blurred vision

 Hypersensitivity to light

 Hypersensitivity to noise

 Other symptoms, specify:

1. If aura symptoms (neurological symptoms that come before or during headache), which type of aura did you have? (Choose all that apply)

Visual aura (flashing lights, zig zag lines, dots, stars, sparkles, blind spots, shape and size distortion, temporary blindness, shimmering patches, tunnel vision, etc.)

Sensory aura (numbness, pins and needles)

Language/Speech aura (trouble understanding speech or producing it)

Motor aura (paralysis/muscle weakness of face, arm, or leg on one side)

Brainstem aura (double-vision, tinnitus or ringing in the ears, increased sense of hearing, unsteadiness when walking, slurred speech, vertigo or spinning sensations, decreased level of alertness)

1. Did this headache reduce your ability to function?  Yes  No

a. How would you describe your abilities to perform your usual daily activities at the onset of this headache?

Able to work and function normally

Working ability or activity impaired to some degree

Working ability or activity severely impaired

Bed rest required

Use the table below to complete how you feel at the designated times after you have taken study medication for this headache (COMPLETE TABLE ONLY IF YOU HAVE TAKEN STUDY MEDICATION):

Table 1: Table for Recording How You Feel AFTER Taking Study Medication

| Time AFTER taking initial study medication | Headache/Migraine Severity:  (complete ***one*** of the following scales) | | Pain Descriptor(s) | Ability to perform daily activities  (Choose only ***one***) | Associated Symptoms  (Choose all that apply) |
| --- | --- | --- | --- | --- | --- |
| 15 minutes  (24 hr clock)  *optional* | 0  6  1  7  2  8  3  9  4  10  5 | None  Mild  Moderate  Severe | Throbbing  Pounding  Stabbing  Constant  Sharp  Pressure  Pulsating  Squeezing  Other, specify: | Able to work and function normally  Working ability or activity impaired to some degree  Working ability or activity severely impaired  Bed rest required | Light sensitivity  Noise sensitivity  Nausea  Vomiting  Aggravation by physical activity |
| 30 minutes  (24 hr clock) | 0  6  1  7  2  8  3  9  4  10  5 | None  Mild  Moderate  Severe | Throbbing  Pounding  Stabbing  Constant  Sharp  Pressure  Pulsating  Squeezing  Other, specify: | Able to work and function normally  Working ability or activity impaired to some degree  Working ability or activity severely impaired  Bed rest required | Light sensitivity  Noise sensitivity  Nausea  Vomiting  Aggravation by physical activity |
| 1 hour  (24 hr clock) | 0  6  1  7  2  8  3  9  4  10  5 | None  Mild  Moderate  Severe | Throbbing  Pounding  Stabbing  Constant  Sharp  Pressure  Pulsating  Squeezing  Other, specify: | Able to work and function normally  Working ability or activity impaired to some degree  Working ability or activity severely impaired  Bed rest required | Light sensitivity  Noise sensitivity  Nausea  Vomiting  Aggravation by physical activity |
| 1.5 hours  (24 hr clock)  *optional* | 0  6  1  7  2  8  3  9  4  10  5 | None  Mild  Moderate  Severe | Throbbing  Pounding  Stabbing  Constant  Sharp  Pressure  Pulsating  Squeezing  Other, specify: | Able to work and function normally  Working ability or activity impaired to some degree  Working ability or activity severely impaired  Bed rest required | Light sensitivity  Noise sensitivity  Nausea  Vomiting  Aggravation by physical activity |
| 2 hours  (24 hr clock) | 0  6  1  7  2  8  3  9  4  10  5 | None  Mild  Moderate  Severe | Throbbing  Pounding  Stabbing  Constant  Sharp  Pressure  Pulsating  Squeezing  Other, specify: | Able to work and function normally  Working ability or activity impaired to some degree  Working ability or activity severely impaired  Bed rest required | Light sensitivity  Noise sensitivity  Nausea  Vomiting  Aggravation by physical activity |
| 4 hours  (24 hr clock)  *optional* | 0  6  1  7  2  8  3  9  4  10  5 | None  Mild  Moderate  Severe | Throbbing  Pounding  Stabbing  Constant  Sharp  Pressure  Pulsating  Squeezing  Other, specify: | Able to work and function normally  Working ability or activity impaired to some degree  Working ability or activity severely impaired  Bed rest required | Light sensitivity  Noise sensitivity  Nausea  Vomiting  Aggravation by physical activity |
| 24 hours  (24 hr clock) | 0  6  1  7  2  8  3  9  4  10  5 | None  Mild  Moderate  Severe | Throbbing  Pounding  Stabbing  Constant  Sharp  Pressure  Pulsating  Squeezing  Other, specify: | Able to work and function normally  Working ability or activity impaired to some degree  Working ability or activity severely impaired  Bed rest required | Light sensitivity  Noise sensitivity  Nausea  Vomiting  Aggravation by physical activity |
| 48 hours  (24 hr clock) | 0  6  1  7  2  8  3  9  4  10  5 | None  Mild  Moderate  Severe | Throbbing  Pounding  Stabbing  Constant  Sharp  Pressure  Pulsating  Squeezing  Other, specify: | Able to work and function normally  Working ability or activity impaired to some degree  Working ability or activity severely impaired  Bed rest required | Light sensitivity  Noise sensitivity  Nausea  Vomiting  Aggravation by physical activity |

1. Complete one of the following:
   1. What time did this headache end? (24 hr clock)
   2. Headache ended after falling asleep?  Yes  No

COMPLETE QUESTION #13 ONLY IF YOU HAVE TAKEN STUDY MEDICATION AND YOUR HEADACHE CAME BACK

If the headache recurred after it was relieved

1. What time did the headache start? (24 hour clock)
2. What time did the headache end? (24 hour clock)
3. Did you take any medications for this headache that re-started?  Yes  No
4. If yes, specify the type of pain medication(s) and time (24 hour format) last taken (choose all that apply):

Another dose of study drug; Time:

Ibuprofen, Time:

Acetaminophen, Time:

Almotriptan, Time:

Aspirin, Time:

Dihydroergotamine (DHE), Time:

Eletriptan, Time:

Ergotamine tartrate (ET), Time:

Frovatriptan, Time:

Naproxen, Time:

Naratriptan, Time:

Rizatriptan, Time:

Sumatriptan, Time:

Zolmitriptan, Time:

Other, specify, Time

## Additional Pediatric-specific Elements

1. Did the headache change the participant’s activity level (i.e., stop playing)?  Yes  No ‘
2. Does activity or playing make the participant’s headache worse?  Yes  No
3. How did today’s headache affect the following school and other activities:

### School

* 1. Participant missed a full day of school?  Yes  No
  2. Participant missed a half or part of the day of school?  Yes  No
  3. Functioned at less than half of participant’s ability at school?  Yes  No

### Home

* 1. Participant could not do things at home (chores, homework, etc.)?  Yes  No

### Other Activities

* 1. Participant could not participate in other activities (sports, play, etc.)?  Yes  No
  2. Participant functioned at less than half of his/her ability?  Yes  N

## General Instructions

This CRF Module is recommended for all headache and migraine studies that have collected headache occurrence data on a daily basis on a headache diary. The information provided in this CRF should be completed and reviewed per the study requirements. All questions are Supplemental Highly- Recommend.

## Specific Instructions

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

* Date/Time – Record the date/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.).
* What time did your headache start? – Record the time the participant/subject’s headache started.
* Did you take any pain medications? – No additional instructions
* If yes, specify the type of pain medication(s) and time last taken– Choose all that apply
* What pain medication(s) other than the study drug did you take? – Choose all that apply
* Which word describes the severity of your headache?
  + For assessing headache pain severity, we have included two scales, (NRS) 0-10, and (ordinal 4-point scale) none, mild, moderate, severe.
* Which of the following describes the pain you feel? – Choose all that apply
* Where is the location of your headache pain? – Choose only one
* Which part(s) of your head hurt(s)? – Choose all that apply
* Did you have any warnings that this headache was going to start? – No additional instructions
  + Which type of warnings did you have today? – Choose all that apply
  + If yes, when did you experience the warning – No additional instructions
* Did you have any of these symptoms associated with this headache?– Choose all that apply
* How would describe your abilities to perform your usual daily activities at the onset of this headache? – No additional instructions
* Timeline Table – Use the table to complete how you feel at the designated times after you have taken study medication for this headache. COMPLETE TABLE ONLY IF YOU HAVE TAKEN STUDY MEDICATION.
  + Time AFTER taking initial– No additional instructions
  + Headache/Migraine Severity– Complete one of the severity scales
  + Ability to perform/daily activities– Choose only one
  + Associated symptoms – Choose all that apply
* What time did this headache end? – Record the time the participant/subject’s headache ended.
* If the headache has ended and restarted afterwards– COMPLETE TABLE ONLY IF YOU HAVE TAKEN STUDY MEDICATION)
  + What time did it start? Record the time the participant/subject’s headache started.
  + What time did it end? Record the time the participant/subject’s headache ended.
  + Did you take any pain medications for this headache that re-started? – No additional instructions
    - If yes, specify the type(s) of pain medication(s) and time last taken– Choose all that apply
* Does activity or play make this headache worse? – This element is recommended for pediatric headache studies.
* How did today’s headache affect the following school and other activities – This element is recommended for pediatric headache studies. The participant’s parents or caregivers can complete these questions.
  + Missed a full day of school? – Choose one.
  + Missed a half or part of the day of school? – Choose one.
  + Functioned at less than half of your ability at school? – Choose one.
  + None of the above, was not a school day – Choose one. Answer should only by ‘Yes’ only if the 3 previous questions were answered ‘No’
  + Could not do things at home (chores, homework, etc.)? – This element is recommended for pediatric headache studies.
  + Could not participate in other activities? – Choose one.
  + Functioned at less than half of his/her ability? – Choose one.

## Reference

Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders, 3rd edition (beta version). Cephalalgia. 2013 Jul;33(9):629-808

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