*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.