MEDICAL HISTORY

|  |
| --- |
| Main group |
| Study Name: |
| **\***GUID (GUID): |
| Subject ID number (SubjectIDNum): | Age in Years (AgeYrs): |
| Visit Date (VisitDate): | Site Name (SiteName): |
| Days since Baseline (DaysSinceBaseline): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Case Control Indicator (CaseContrlInd):Case ⭘ Control ⭘ Unknown  | What is the vital status of the subject? (VitStatus):O Alive ⭘ Dead ⭘ Unknown |

|  |
| --- |
| Form administration |
| What is the ISO 639 code for the language the form/instrument has been administrated? (LangCRFAdministratISOCode). Select one. If “Other, specify” is selected, please write in response.

|  |  |
| --- | --- |
| chi Chinesecze Czechdan Danishdut Dutcheng Englishfin Finnishfre French ger Germangre Greekheb Hebrewhin Hindihun Hungarian | ira Iranian languages ita Italianjpn Japanesenor Norwegianpor Portugueserus Russiansgn Sign languagespa Spanishvie VietnameseOther, specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (LangCRFAdministratISOCodeOTH) |

What time frame do the questions in this form refer to? (ContextType)Select one. If “Other, specify” is selected, please write in response.* After injury
* At time of assessment
* Time of injury
* Before injury
* Last 2 weeks
* Last 6 months
* Last 24 hours
* Last month
* Last week
* Last year
* Prior to death
* Since last interview
* Other, specify (ContextTypeOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 |
| Who filled out this form? (DataSource)Select one. If “Other, specify” is selected, please write in response. * Participant/Subject
* Spouse
* Father
* Mother
* Son
* Daughter
* Brother
* Sister
* Friend
* Physician
* Chart/Medical Record
* Other, specify (DataSourceOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 |

# Birth history

Were you told by a doctor or one of your parents that you were born premature (BornPrematurInd)? Chooseone.

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Gestational age at birth (GestatnlAgeVal) in weeks\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

APGAR 1-minute score (APGAR1MinScore). *Choose one*.:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| O 1 | O 2 | O 3 | O 4 | O 5 |
| O 6 | O 7 | O 8 | O 9 | O 10 |

APGAR 5-minute score (APGARFiveMinuteScore). *Choose one*:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| O 1 | O 2 | O 3 | O 4 | O 5 |
| O 6 | O 7 | O 8 | O 9 | O 10 |

APGAR 10-minute score (APGARTenMinuteScore). *Choose one*.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| O 1 | O 2 | O 3 | O 4 | O 5 |
| O 6 | O 7 | O 8 | O 9 | O 10 |

Birth weight (BirthWgtVal) in grams \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Perinatal neurologic event if any (PerinatlNeurolEventTyp).
 *Select all that apply. If “Other, specify” is selected, provide an input.*

* Traventricular hemorrhage
* None
* Subarachnoid hemorrhage
* Subdural hemorrhage
* Other, specify (PerinatlNeurolEventOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Any problems during neonatal period (NeonatProblemInd)? *Choose one*.

* Yes, specify (NeonatalProblemOtherText) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* No
* Unknown

Any neonatal intensive care unit (NICU) stay (NICUStayInd)? *Choose one*.

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

If “Yes”, length of NICU stay (NICUStayDur)? *Choose one*.

* <=48 hours
* >48 hours and <1 week
* >=1 week

Postnatal age value (PNA) (PostnatalAgeVal) in days\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Past Medical History Global Assessment

Specify if the participant/subject has or had a history of any medical problems/conditions in the following body systems (MedclHistBodySysInd)? *Choose one*.

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Body system category (BodySysCat).
*Select all that apply. If "Other, specify" is selected, provide an input.*

|  |  |
| --- | --- |
| * Allergic/Immunologic
* Cardiovascular
* Constitutional symptoms (e.g., fever, weight loss)
* Dermatological
* Ears, Nose, Mouth, Throat
* Endocrine
* Eyes
* Gastrointestinal
* Gastrointestinal/Abdominal
* Genitourinary
* Gynecologic/Urologic/ Renal
* Hematologic/Lymphatic
* Hepatobiliary
 | * Integumentary (skin and/or breast)
* Musculoskeletal
* Musculoskeletal (separate from ALS exam)
* Neurological
* Neurological (separate from ALS exam)
* Neurologic/CNS
* Oncologic
* Psychiatric
* Pulmonary
* Respiratory
* Other, specify (BodySysOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 |

Date medical history taken (MedclHistTakenDateTime) \_\_\_\_\_\_\_\_\_\_\_

Medical history condition start date and time
(MedclHistCondStrtDateTime) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

End date and time (MedclHistCondEndDateTime) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

SNOMED CT code (MedclHistCondSNOMEDCTCode**\***)
Enter SNOMED CT code. List multiple codes if needed. Use Appendix 3 “cheat sheet” to find the codes. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history condition text (MedclHistCondTxt**\***)
For each SNOMED CT code listed in MedclHistCondSNOMEDCTCode, enter the verbatim concept name. Use Appendix 3 “cheat sheet” to find the codes and names. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# ONGOING Medical History Global Assessment

Specify if the participant/subject has or had a history of any medical problems/conditions in the following body systems (MedclHistBodySysInd)? *Choose one*:

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Body system category (BodySysCat).
 *Select all that apply. If “Other, specify” is selected, provide an input.*

|  |  |
| --- | --- |
| * Allergic/Immunologic
* Cardiovascular
* Constitutional symptoms (e.g., fever, weight loss)
* Dermatological
* Ears, Nose, Mouth, Throat
* Endocrine
* Eyes
* Gastrointestinal
* Gastrointestinal/Abdominal
* Genitourinary
* Gynecologic/Urologic/ Renal
* Hematologic/Lymphatic
* Hepatobiliary
 | * Integumentary (skin and/or breast)
* Musculoskeletal
* Musculoskeletal (separate from ALS exam)
* Neurological
* Neurological (separate from ALS exam)
* Neurologic/CNS
* Oncologic
* Psychiatric
* Pulmonary
* Respiratory
* Other, specify (BodySysOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 |

Date medical history taken (MedclHistTakenDateTime) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history condition start date and time
(MedclHistCondStrtDateTime) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

End date and time (MedclHistCondEndDateTime) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

SNOMED CT code (MedclHistCondSNOMEDCTCode**\***)
Enter SNOMED CT code. List multiple codes if needed. Use Appendix 3 “cheat sheet” to find the codes. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history condition text (MedclHistCondTxt**\***)
For each SNOMED CT code listed in MedclHistCondSNOMEDCTCode, enter the verbatim concept name. Use Appendix 3 “cheat sheet” to find the codes and names. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Hospitalizations

Whether the subject was hospitalized before (HospitalizationsInd)? *Choose one*:

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Was a non-surgical hospitalization elective (HosptlizatnNonSurgElectvInd)?

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Have you ever been hospitalized for an alcohol-related problem (AlcUseRelatedHospInd)? *Choose one*:

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Describe a cause for hospitalization (HospitRsn). *Select all that apply. If “Other, specify” is selected, provide an input.*

|  |  |
| --- | --- |
| * Cardiomyopathy/Arrhythmia
* Dehydration
* Failure to Thrive
* Fracture
* Infection other than pneumonia
 | * Pneumonia or Respiratory
* Seizures
* Trauma
* Other, specify (HospitOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 |

Indicate the number of hospitalizations the participant had in the past year (HospitPastYrCt) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Number of hospitalizations (HosptlizatnNonSurgNum) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Any surgical procedures performed (SurgTherProcedurPerfInd)? *Choose one*:

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

# History of TBIs

Prior traumatic injury indicator (PriorTraumInjryInd). *Choose one*:

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Prior traumatic injury type (PriorTraumInjryType).
 *Select all that apply. If “Other, specify” is selected, provide an input.*

|  |  |  |
| --- | --- | --- |
| * Brain Injury
 | * Spine Injury
 | * Other Extracranial Injury
 |

SNOMED CT code (MedclHistCondSNOMEDCTCode**\***) Enter SNOMED CT code. List multiple codes if needed. Use Appendix 3 “cheat sheet” to find the codes. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history condition text (MedclHistCondTxt**\***) For each SNOMED CT code listed in MedclHistCondSNOMEDCTCode, enter the verbatim concept name. Use Appendix 3 “cheat sheet” to find the codes and names. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Number of concussions prior to the current injury (ConcussionPriorNum)
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Head injury prior number (HeadInjPriorNum) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# History of Headaches/Migraines

What time frame do the questions in this form refer to? (ContextType)
*Select one. If “Other, specify” is selected, please write in response*.

* After injury
* At time of assessment
* Time of injury
* Before injury
* Last 2 weeks
* Last 6 months
* Last 24 hours
* Last month
* Last week
* Last year
* Prior to death
* Since last interview
* Other, specify (ContextTypeOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Does the participant/subject suffer(ed) from headaches (HeadachHistInd)? *Choose one*:

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Was the participant/subject diagnosed with headaches and/or migraines (HeadachMigranDiagnsInd)? *Choose one*:

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Diagnosis provided (HeadachMigranTyp)
*Select all that apply*

* Chronic Migraine
* Chronic Tension Type
* Cluster Headache
* Episodic Tension Type
* Hemiplegic Migraine
* Menstrual Headache
* Migraine with aura
* Migraine without aura
* Other TAC type, specify
* Tension Type Headache
* Trigeminal Autonomic Cephalgias
* Trigeminal Headache
* Other primary/secondary type headache, specify (AddtnalCommntTxt)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Did headache change your activity level (i.e., stop playing) (HeadachAffctActvtyLvlInd)? *Choose one*:

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Actual average number of days per month the participant/subject had headaches in the past 3 months (based on a 30 day month) (HeadachAveDayMonthCt):
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

How often do your headaches occur (HeadachFreq)? *Choose one*:

* Once per day
* Once per week
* 2-4 times per week
* 5-6 times per week
* 1-3 times per month
* Less than once per month

Describe the typical pain severity for your headache (HeadachTypclSevertyTyp):

* None
* Mild
* Moderate
* Severe

Does this recent 3 month frequency represent a change compared to the prior 3 months (HeadachFreqChngInd)? *Choose one*:

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

If yes, specify change in the subject’s headache pain severity (HeadachFreqChngTyp). *Choose one*:

* Decreased
* Increased
* Unchanged

When the participant/subject has a headache, does he/she experience any of the following (HeadachTypclAssctSymptmTyp).
*Select all that apply. If “Other, specify” is selected, provide an input.*

* Dizziness
* Increased neck pain or stiffness
* Increased sensitivity to light
* Increased sensitivity to noise
* Increased sensitivity to smell
* Nausea
* Non-vertigo
* One-sided numbness of lips, tongue, fingers, or legs that migrates or moves and starts before the headache becomes severe and lasts less than an hour
* Pain made worse by routine activity
* Pain on one side of head only
* Pulsating/throbbing headaches
* Seeing shimmering lights, lines, dark spots, other shapes or colors before the eyes, before or during the headache and lasts more than a few minutes but less than an hour
* Vertigo
* Vomiting
* Weakness on one side

If severe, which of the following best describes how the participant/subject is usually affected (HeadachTypclLvlActvtyAffctRslt)? *Choose one*:

* Able to work/function normally
* Bed rest required
* Working ability or activity impaired to some degree
* Working ability or activity severely impaired

Rate the typical headache pain on a scale of 0-10
(HeadacheTypPainIntstyRateScale) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Study Medications

Has the participant/ subject ever taken study prescribed medications, investigational medications, or supplements (MedctnSupplUseInd)?
*Choose one:*

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Is the study medication use ongoing (MedicationStudyOngoingInd)?
*Choose one.*

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Medication study name (trade of generic) (MedicationStudyName) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Start day and time if applicable of study medication (StdyDrugStrtDateTime) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

End day and time if applicable of study medication (StdyDrugEndDateTime) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reason for taking the study medication (MedicationStudyReasonTxt) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dose of study medication taken per administration (StdyDrugDose) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Record the unit for dose of study drug the subject was prescribed to take (StdyDrugDoseUoM)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Code the unit for measure for the dosage of study drug using Unified Code for Units of Measure (UCUM). http://unitsofmeasure.org/ (StdyDrugDoseUoMUCUMCd) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Record the frequency participant/subject was prescribed to take the dose of study drug. (StdyDrugDoseFreq)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study medication route (MedicationStudyRteTyp)
*Select all that apply*

|  |  |
| --- | --- |
| * Buccal
* By Ear
* Inhaled
* Intramuscular
* Intravenous
* Nasal
* Oral
* Rectal
 | * Subcutaneous
* Sublingual
* Topical
* Transdermal
* Unknown
* Other, specify (MedicationStudyRteTypOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 |

Medication study description response text (MedicationStudyResponseTxt)
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medication study formulation text (StdyDrugDosageFormTxt) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study medication average frequency (MedicationStudyPRNAMonthFreq) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study medication RXNorm code (MedicationStudyRxNormCode) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If applicable, reason for discontinuation (MedicationStudyDiscontRsnTxt) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Medications Concomitant

Is the participant/ subject talking any physician prescribed medications, investigational medications, or supplements? (MedctnSupplUseInd). *Choose one*:

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Medication/supplement name (MedctnSupplName) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Is the subject taking any non-study medications (MedctnPriorConcomUseInd)?
*Choose one:*

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Concomitant medication name (trade of generic) (MedctnPriorConcomName)
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

RXNorm code (MedctnPriorConcomRxNormCode)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reason for taking the medication (MedctnPriorConcomIndTxt)
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Is the concomitant medication use ongoing (MedctPrConcomOngoingInd)?
*Choose one:*

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Concomitant medication start date (MedctnPriorConcomStrtDateTime)
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Concomitant medication end date (MedctnPriorConcomEndDateTime)
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dose taken per administration (MedctnPriorConcomDose)
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dosage unit of measure (MedctnPriorConcomDoseUo)
*Choose one. If "Other, specify" is selected, provide an input.*

* Gram
* Microgram
* Microliter
* Milligram
* Milliliter
* Ounce
* Not applicable
* Other, specify (MedicationPriorConcomDoseUoMOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dose unit of measure UCUM code (MedctnPriorConcomDoseUoMUCUMCd)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dose frequency (MedctnPriorConcmtntDoseFreq)
*Choose one. If "Other, specify" is selected, provide an input*

* alternating day (every other day)
* twice daily
* at bedtime
* as needed
* every 2 hours
* every 4 hours
* every 6 hours
* every 8 hours
* one dose in morning
* once daily
* four times a day
* one dose in evening
* three times a day
* unknown
* not applicable
* Other, specify (MedctnPriorConcmtntDoseFreqOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Type of access route for the administration of the medication (MedctnPriorConcomRteTy)
*Select all that apply. If "Other, specify" is selected, provide an input*

|  |  |
| --- | --- |
| * Buccal
* By Ear
* Inhaled
* Intramuscular
* Intravenous
* Nasal
* Oral
 | * Rectal
* Subcutaneous
* Sublingual
* Topical
* Transdermal
* Unknown
* Other, specify (MedctnPriorConcomRteOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 |

Any adverse event related to medication, provide the adverse event tracking number (AdverseEventTrackNum)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Medications Prior

Did the participant/ subject ever take any physician prescribed medications, investigational medications, or supplements? (MedctnSupplUseInd). *Choose one*:

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Medication/supplement name (MedctnSupplName) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Did the subject ever taken any non-study medications (MedctnPriorConcomUseInd)? *Choose one:*

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Prior medication name (trade of generic) (MedctnPriorConcomName)
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

RXNorm code (MedctnPriorConcomRxNormCode) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reason for taking the medication (MedctnPriorConcomIndTxt) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Is the concomitant medication use ongoing (MedctPrConcomOngoingInd)?
*Choose one:*

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Prior medication start date (MedctnPriorConcomStrtDateTime)
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Prior medication end date (MedctnPriorConcomEndDateTime)
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dose taken per administration (MedctnPriorConcomDose)
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dosage unit of measure (MedctnPriorConcomDoseUo)\_\_\_\_\_\_\_\_\_
*Choose one. If "Other, specify" is selected, provide an input*

* Gram
* Microgram
* Microliter
* Milligram
* Milliliter
* Ounce
* Not applicable
* Other, specify (MedicationPriorConcomDoseUoMOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_

Dose unit of measure UCUM code (MedctnPriorConcomDoseUoMUCUMCd)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dose frequency (MedctnPriorConcmtntDoseFreq)
*Choose one. If "Other, specify" is selected, provide an input*

* alternating day (every other day)
* twice daily
* at bedtime
* as needed
* every 2 hours
* every 4 hours
* every 6 hours
* every 8 hours
* one dose in morning
* once daily
* four times a day
* one dose in evening
* three times a day
* unknown
* not applicable
* Other, specify (MedctnPriorConcmtntDoseFreqOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Type of access route for the administration of the medication (MedctnPriorConcomRteTy)
*Select all that apply. If "Other, specify" is selected, provide an input*

* Buccal
* By Ear
* Inhaled
* Intramuscular
* Intravenous
* Nasal
* Oral
* Rectal
* Subcutaneous
* Sublingual
* Topical
* Transdermal
* Unknown
* Other, specify (MedctnPriorConcomRteOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Any adverse event related to medication, provide the adverse event tracking number (AdverseEventTrackNum)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Allergies

 Does the subject have any allergies (AllergyDiagnInd)?
*Choose one:*

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

If yes, check which type (AllergyReportedTyp)
*Choose all that apply:*

* Food
* Medication
* Seasonal
* Other, specify (AllergyReportedTypOTH)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Allergy description (AllergyDescriptionTxt). Enter the descriptive test. Include the list or allergens:
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Allergic reaction type (AllergyReportedReactTyp). *Choose all that apply for each allergy type from the previous question*:

* Anaphylaxis
* Difficulty breathing
* Dizziness
* Headaches
* Hives
* Itching
* Nausea
* Rash
* Swelling
* Vomiting
* Other, specify (AllergyReportedReactTypOTH)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Behavioral History

What time frame do the questions in this section refer to? (ContextType)
Select one. If “Other, specify” is selected, please write in response.

* After injury
* At time of assessment
* Time of injury
* Before injury
* Last 2 weeks
* Last 6 months
* Last 24 hours
* Last month
* Last week
* Last year
* Prior to death
* Since last interview
* Other, specify (ContextTypeOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Current drinker(AlcCurntUseInd)
*Choose one:*

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Past drinker(AlcPriorUseInd)? *Choose one*:

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Duration (in years) the participant/subject has used alcohol (ingesting of alcoholic beverages, including social drinking (AlcoholUseDuratn)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

During the past 30 days, how many days per month did you have at least one drink of any alcoholic beverage such as beer, wine, a malt beverage or liquor(AlcoholUseLastMoDayDrnkNum)?

During the past 30 days, on the days when you drank, about how many drinks did you drink on the average? NOTE: One drink is equivalent to a 12-ounce beer, a 5-ounce glass of wine, or a drink with one shot of liquor. A 40 ounce beer would count as 3 drinks, or a cocktail drink with 2 shots would count as 2 drinks. (AlchlUseLstMoDrnkDyAvgDrnksNum)?

Considering all types of alcoholic beverages, how many times during the past 30 days did you have X [X = 5 for men, X = 4 for women] or more drinks on an occasion (AlcohlLstMoConsmOvr5DrnkDayNum)?

Age started drinking (AlcUseStrtAgeVal)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Age quit drinking (AlcUseStopAgeVal)

Drug or substance prior illicit use (DrugSubstncPriorIllictUseInd)?
*Choose one:*

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |
|  |  |  |
|  |  |  |

Current drug user (DrgSubstCurrntIllicitUseCat)?
*Choose one.*

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

If YES, specify illicit drug type(s) used (DrgSubIllctUseCat)

* Cocaine or crack
* Hallucinogens (e.g., Ecstasy, LSD, mescaline, psilocybin, PCP, angel dust, or peyote)
* Heroin
* Inhalants or Solvents (e.g., amyl nitrate, nitrous oxide, glue, tolune, or gasoline
* Marijuana, hash, THC, or grass
* Other, specify (e.g., Methadone, Elavil, steroids, Thorazine, or Haldol)
* Painkillers (e.g., Codeine, Darvon, Percodan, Dilaudid, or Demerol)
* Sedatives (e.g., sleeping pills, barbiturates, Seconal, Quaaludes, or Chloral Hydrate)
* Stimulants (e.g., Preludin, Benzedrine, Methadrine, uppers, or speed)
* Tranquilizers or anti-anxiety drugs (e.g., Valium, Librium, muscle relaxants, or Zanax)

Total years use of illicit drugs (DrgSubsIllctUseDur)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Current tobacco use (TobcoUseCurntInd)?
*Choose one:*

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Past tobacco use (TobcoPriorUseInd)?
*Choose one:*

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Duration in years participant/subject has used tobacco products (e.g. cigarettes, cigars, chewing tobacco or pipe) (TobcoUseDur)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Type(s) of tobacco used (TobcoProdctUsedTyp)
*Select all that apply*

* Chewing tobacco
* Cigars
* Filtered cigarettes
* Low tar cigarettes
* Non-filtered cigarettes
* Pipes
* Other, specify (TobcoProdctUsedOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Drug Screen Test

Whether a drug screen was performed (DrugScreenInd)?
*Choose one*

* Yes
* No

Drug screen qualitative result (DrgScrnQualReslt)
*Choose one*

* Positive
* Negative
* Inconclusive
* Not available

Drug screen sample type (DrgScrnSamplTyp)
*Choose one*

* Hair
* Saliva
* Serum
* Urine
* Other, specify (DrgScrnSamplOTH)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Drug screen positive type (DrgScrnPosSubstncTyp)
*Select all that apply*

* Amphetamines
* Barbiturates
* Benzodiazepines
* Cocaine metabolite
* Marijuana metabolites
* Methadone
* Opiates (codeine and morphine)
* Phencyclidine
* Propoxyphene
* Other, specify (DrgScrnPosSubstncOTH)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Reasonable accommodations

Any reasonable accommodations required? (ReasonAccommodRequiredInd). Choose one:

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Type of conditions that require reasonable accommodations (ReasonAccommodTyp). *Select all that apply:*

* Blind
* Deaf
* Decreased hand function
* Hard of hearing
* Low vision
* Mobility impairment
* Reading impairment
* Speech impairment
* Unknown
* Not reported
* Other, specify (ReasonAccommodTypOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reasonable accommodations accessibility (ReasonAccommodAccessTyp). *Select all that apply:*

* Accessibility depends on severity of mobility impairment
* Currently accessible
* Not accessible and not feasible to make accessible
* Not accessible, but can be made accessible with reasonable accommodations
* Not applicable
* Other, specify (ReasonAccommodAccessTyp)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# APPENDIX 1: MEDICAL HISTORY CODES

Use this part of the form if you collected medical history codes using Medical History form from TBI Impact (http://www.tbi-impact.org/cde/mod\_templates/T\_6.%20Medical%20History%209.1.pdf)

## Past Medical History Codes

1. Specify if participant/subject has a history of any medical problems/conditions in the following body systems (MedclHistGlobalAssmtInd)?
*Choose one:*

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Medical history cardiovascular category (MedHistCodeCardio)
 *Select all that apply. If “Other, specify” is selected, provide an input.*

* 012-Arrhythmia
* 011-Congenital heart disease
* 015-Hypertension
* 013-Ischemic heart disease
* 017-Peripheral vascular disease
* 016-Thromboembolic
* 014-Valvular heart disease
* 019-Other, specify (MedHistCodeCardioOTH) \_\_\_\_\_\_\_\_\_\_\_

Medical history developmental history category (MedHistDevelopmentalHistory):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* 142-Attention deficit/hyperactivity disorder
* 143-Developmentally Delayed
* 141-Learning disabilities
* 144-Other developmental disorder
* 149-Other, specify (MedHistDevelopmentalHistoryOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history endocrine category (MedHistEndocrine):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* 022-IDDM (Type I)
* 023-NIDDM (Type II)
* 021-Thyroid disorder
* 029-Other, specify (MedHistEndocrineOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history eye, ear, nose, and throat category (MedHistEyeEarNoseThroat):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* 033-Hearing deficit
* 031-Sinusitis
* 032-Vision abnormality
* 039-Other, specify (MedHistEyeEarNoseThroatOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history gastrointestinal category (MedHistGastrointestinal):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* 044-Diarrhea secondary
* 041-GERD
* 042-GI bleed
* 043-Inflammatory bowel disease
* 049-Other, specify (MedHistGastrointestinalOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history hematologic category (MedHistHematologic):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* 053-AIDS
* 051-Anemia
* 055-Coagulopathy
* 052-HIV positive
* 054-Sickle cell disease
* 059-Other, specify (MedHistHematologicOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history hepatic category (MedHistHepatic):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* 064-Cirrhosis
* 062-Failure
* 063-Hepatitis
* 061-Insufficiency
* 069-Other, specify MedHistHepaticOTH

Medical history musculoskeletal category (MedHistMusculoskeletal):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* 071-Arthritis
* 073-Pressure ulcers
* 072-Spasticity
* 079-Other, specify (MedHistMusculoskeletalOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history neurologic category (MedHistNeurologic):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* Cerebral vascular anomaly
* 081-Cerebrovascular accident
* 085-Epilepsy: focal
* 086-Epilepsy: other
* 084-Epilepsy: partial
* 087-Headache (non-migraine)
* 088-Migraine headaches
* 089-Previous TBI
* 083-Seizures
* 083-Seizures-Alcohol
* 083-Seizures-Febrile
* 083-Seizures-Idiopathic
* 083-Seizures - Posttraumatic
* Spinal cord injury
* 082-Transient ischemic attacks
* Tumor
* Vertebral injury
* Other, specify (MedHistNeurologicOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history oncologic category (MedHistOncologic):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* Cerebral vascular anomaly
* 081-Cerebrovascular accident
* 085-Epilepsy: focal
* 086-Epilepsy: other
* 084-Epilepsy: partial
* 087-Headache (non-migraine)
* 088-Migraine headaches
* 089-Previous TBI
* 083-Seizures
* 083-Seizures-Alcohol
* 083-Seizures-Febrile
* 083-Seizures-Idiopathic
* 083-Seizures - Posttraumatic
* Spinal cord injury
* 082-Transient ischemic attacks
* Tumor
* Vertebral injury
* Other, specify (MedHistOncologicOTH)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history psychiatric category (MedHistPsychiatric):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* 111-Anxiety
* 112-Depression
* 115-Other psychiatric disorder
* 114-Schizophrenia
* 113-Sleep Disorder
* 119-Other, specify (MedHistPsychiatricOTH)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history pulmonary category (MedHistPulmonary):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* 102-Asthma
* 101-COPD
* 103-Pneumonia
* 104-Tuberculosis
* 109-Other, specify (MedHistPulmonaryOTH)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history renal category (MedHistRenal):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* 123-Chronic UTI's
* 122-Failure
* 121-Insufficiency
* 129-Other, specify (MedHistRenalOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history social history category (MedHistSocialHistory):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* 132-Alchohol use
* 133-Drug use
* 131-Tobacco use
* 139-Other, specify (MedHistSocialHistoryOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Ongoing Medical History Codes

1. Specify if participant/subject has a history of any medical problems/conditions in the following body systems (MedclHistGlobalAssmtInd)?
*Choose one:*

|  |  |  |
| --- | --- | --- |
| * Yes
 | * No
 | * Unknown
 |

Medical history cardiovascular category (MedHistCodeCardio)
 *Select all that apply. If “Other, specify” is selected, provide an input.*

* 012-Arrhythmia
* 011-Congenital heart disease
* 015-Hypertension
* 013-Ischemic heart disease
* 017-Peripheral vascular disease
* 016-Thromboembolic
* 014-Valvular heart disease
* 019-Other, specify (MedHistCodeCardioOTH) \_\_\_\_\_\_\_\_\_\_\_

Medical history developmental history category (MedHistDevelopmentalHistory):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* 142-Attention deficit/hyperactivity disorder
* 143-Developmentally delayed
* 141-Learning disabilities
* 144-Other developmental disorder
* 149-Other, specify (MedHistDevelopmentalHistoryOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history endocrine category (MedHistEndocrine):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* 022-IDDM (Type I)
* 023-NIDDM (Type II)
* 021-Thyroid disorder
* 029-Other, specify (MedHistEndocrineOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history eye, ear, nose, and throat category (MedHistEyeEarNoseThroat):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* 033-Hearing deficit
* 031-Sinusitis
* 032-Vision abnormality
* 039-Other, specify (MedHistEyeEarNoseThroatOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history gastrointestinal category (MedHistGastrointestinal):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* 044-Diarrhea secondary to
* 041-GERD
* 042-GI bleed
* 043-Inflammatory bowel disease
* 049-Other, specify (MedHistGastrointestinalOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history hematologic category (MedHistHematologic):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* 053-AIDS
* 051-Anemia
* 055-Coagulopathy
* 052-HIV positive
* 054-Sickle cell disease
* 059-Other, specify (MedHistHematologicOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history hepatic category (MedHistHepatic):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* 064-Cirrhosis
* 062-Failure
* 063-Hepatitis
* 061-Insufficiency
* 069-Other, specify (MedHistHepaticOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history musculoskeletal category (MedHistMusculoskeletal):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* 071-Arthritis
* 073-Pressure ulcers
* 072-Spasticity
* 079-Other, specify (MedHistMusculoskeletalOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history neurologic category (MedHistNeurologic):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* Cerebral vascular anomaly
* 081-Cerebrovascular accident
* 085-Epilepsy: focal
* 086-Epilepsy: other
* 084-Epilepsy: partial
* 087-Headache (non-migraine)
* 088-Migraine headaches
* 089-Previous TBI
* 083-Seizures
* 083-Seizures-Alcohol
* 083-Seizures-Febrile
* 083-Seizures-Idiopathic
* 083-Seizures - Posttraumatic
* Spinal cord injury
* 082-Transient ischemic attacks
* Tumor
* Vertebral injury
* Other, specify (MedHistNeurologicOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history oncologic category (MedHistOncologic):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* Cerebral vascular anomaly
* 081-Cerebrovascular accident
* 085-Epilepsy: focal
* 086-Epilepsy: other
* 084-Epilepsy: partial
* 087-Headache (non-migraine)
* 088-Migraine headaches
* 089-Previous TBI
* 083-Seizures
* 083-Seizures-Alcohol
* 083-Seizures-Febrile
* 083-Seizures-Idiopathic
* 083-Seizures - Posttraumatic
* Spinal cord injury
* 082-Transient ischemic attacks
* Tumor
* Vertebral injury
* Other, specify (MedHistOncologicOTH)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history psychiatric category (MedHistPsychiatric):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* 111-Anxiety
* 112-Depression
* 115-Other psychiatric disorder
* 114-Schizophrenia
* 113-Sleep Disorder
* 119-Other, specify (MedHistPsychiatricOTH)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history pulmonary category (MedHistPulmonary):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* 102-Asthma
* 101-COPD
* 103-Pneumonia
* 104-Tuberculosis
* 109-Other, specify (MedHistPulmonaryOTH)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history renal category (MedHistRenal):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* 123-Chronic UTI's
* 122-Failure
* 121-Insufficiency
* 129-Other, specify (MedHistRenalOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical history social history category (MedHistSocialHistory):
*Select all that apply. If “Other, specify” is selected, provide an input.*

* 132-Alchohol use
* 133-Drug use
* 131-Tobacco use
* 139-Other, specify (MedHistSocialHistoryOTH) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# APPENDIX 2: CORE TBI Data Elements

|  |
| --- |
| TBI core CDEs are highlighted with a red asterisk. |
| Variable Name | **Page number** |
| GUID | 1 |
| MedclHistCondTxt | 5,6,8 |
| MedclHistCondSNOMEDCTCode | 5,6,8 |

# APPENDIX 3: Some SNOMED Concept Codes and Verbatim Text

|  |  |
| --- | --- |
| **SNOMED Concept Code** | **Medical History SNOMED Concept Verbatim Name** (https://phinvads.cdc.gov/vads/) |
| 441806004 | Abscess of brain |
| 702632000 | Acquired brain injury (disorder) |
| 209922004 | Brain contusion with open intracranial wound, with 1-24 hours loss of consciousness |
| 209921006 | Brain contusion with open intracranial wound, with more than 1 hour loss of consciousness |
| 209923009 | Brain contusion with open intracranial wound, with more than 24 hours loss of consciousness and return to pre-existing conscious level |
| 209924003 | Brain contusion with open intracranial wound, with more than 24 hours loss of consciousness without return to pre-existing conscious level |
| 209920007 | Brain contusion with open intracranial wound, with no loss of consciousness |
| 2470005 | Brain damage |
| 275272006 | Brain damage - traumatic |
| 28188001 | Brain injury with open intracranial wound |
| 28156009 | Brain injury with open intracranial wound AND brief loss of consciousness (less than one hour) |
| 5202009 | Brain injury with open intracranial wound AND concussion |
| 13752003 | Brain injury with open intracranial wound AND loss of consciousness |
| 86010003 | Brain injury with open intracranial wound AND moderate loss of consciousness (1-24 hours) |
| 12912004 | Brain injury with open intracranial wound AND no loss of consciousness |
| 27923006 | Brain injury with open intracranial wound AND prolonged loss of consciousness (more than 24 hours) AND return to pre-existing conscious level |
| 86488006 | Brain injury with open intracranial wound AND prolonged loss of consciousness (more than 24 hours) without return to pre-existing conscious level |
| 9015001 | Brain injury without open intracranial wound |
| 22693008 | Brain injury without open intracranial wound AND with brief loss of consciousness (less than one hour) |
| 33332005 | Brain injury without open intracranial wound AND with concussion |
| 53267002 | Brain injury without open intracranial wound AND with loss of consciousness |
| 47450003 | Brain injury without open intracranial wound AND with moderate loss of consciousness (1-24 hours) |
| 79228001 | Brain injury without open intracranial wound AND with no loss of consciousness |
| 55885004 | Brain injury without open intracranial wound AND with prolonged loss of consciousness (more than 24 hours) with return to pre-existing conscious level |
| 47462004 | Brain injury without open intracranial wound AND with prolonged loss of consciousness (more than 24 hours) without return to pre-existing conscious level |
| 39020005 | Brain injury, without skull fracture |
| 25816005 | Brain stem compression |
| 127305005 | Brain stem contusion |
| 78968003 | Brain stem contusion with open intracranial wound |
| 57012007 | Brain stem contusion with open intracranial wound AND brief loss of consciousness (less than one hour) |
| 78028004 | Brain stem contusion with open intracranial wound AND concussion |
| 66393002 | Brain stem contusion with open intracranial wound AND loss of consciousness |
| 23026001 | Brain stem contusion with open intracranial wound AND moderate loss of consciousness (1-24 hours) |
| 52913008 | Brain stem contusion with open intracranial wound AND no loss of consciousness |
| 16837005 | Brain stem contusion with open intracranial wound AND prolonged loss of consciousness (more than 24 hours) AND return to pre-existing conscious level |
| 42670008 | Brain stem contusion with open intracranial wound AND prolonged loss of consciousness (more than 24 hours) without return to pre-existing conscious level |
| 52888005 | Brain stem contusion without open intracranial wound |
| 54637009 | Brain stem contusion without open intracranial wound AND with brief loss of consciousness (less than one hour) |
| 79220008 | Brain stem contusion without open intracranial wound AND with concussion |
| 29807001 | Brain stem contusion without open intracranial wound AND with loss of consciousness |
| 38761006 | Brain stem contusion without open intracranial wound AND with moderate loss of consciousness (1-24 hours) |
| 36716000 | Brain stem contusion without open intracranial wound AND with no loss of consciousness |
| 10061007 | Brain stem contusion without open intracranial wound AND with prolonged loss of consciousness (more than 24 hours) AND return to pre-existing conscious level |
| 63023005 | Brain stem contusion without open intracranial wound AND with prolonged loss of consciousness (more than 24 hours) without return to pre-existing conscious level |
| 95454007 | Brain stem hemorrhage |
| 63986002 | Brain stem herniation |
| 95457000 | Brain stem infarction |
| 95456009 | Brain stem ischemia |
| 127307002 | Brain stem laceration |
| 12589008 | Brain stem laceration with open intracranial wound |
| 6147005 | Brain stem laceration with open intracranial wound AND brief loss of consciousness (less than one hour) |
| 41222005 | Brain stem laceration with open intracranial wound AND concussion |
| 3119002 | Brain stem laceration with open intracranial wound AND loss of consciousness |
| 41025001 | Brain stem laceration with open intracranial wound AND moderate loss of consciousness (1-24 hours) |
| 19210000 | Brain stem laceration with open intracranial wound AND no loss of consciousness |
| 5073009 | Brain stem laceration with open intracranial wound AND prolonged loss of consciousness (more than 24 hours) AND return to pre-existing conscious level |
| 64413001 | Brain stem laceration with open intracranial wound AND prolonged loss of consciousness (more than 24 hours) without return to pre-existing conscious level |
| 20899000 | Brain stem laceration without open intracranial wound |
| 59561005 | Brain stem laceration without open intracranial wound AND with brief loss of consciousness (less than one hour) |
| 17819003 | Brain stem laceration without open intracranial wound AND with concussion |
| 10256000 | Brain stem laceration without open intracranial wound AND with loss of consciousness |
| 18531006 | Brain stem laceration without open intracranial wound AND with moderate loss of consciousness (1-24 hours) |
| 78525006 | Brain stem laceration without open intracranial wound AND with no loss of consciousness |
| 70686002 | Brain stem laceration without open intracranial wound AND with prolonged loss of consciousness (more than 24 hours) AND return to pre-existing conscious level |
| 67378005 | Brain stem laceration without open intracranial wound AND with prolonged loss of consciousness (more than 24 hours) without return to pre-existing conscious level |
| 51568001 | Brain stem vertigo |
| 230807001 | Brain ventricular shunt displacement |
| 444869007 | Cavernous hemangioma of brain |
| 191475009 | Chronic alcoholic brain syndrome |
| 78689005 | Chronic brain syndrome |
| 15139001 | Chronic brain-hydrocephalus syndrome |
| 429271000124103 | Chronic hypoxic-ischemic brain injury |
| 27195007 | Chronic non-psychotic brain syndrome |
| 111033008 | Circumscribed atrophy of brain |
| 209871005 | Closed hindbrain contusion |
| 10481000119108 | Colloid brain cyst |
| 46963008 | Compression of brain |
| 141091000119105 | Compression of brain co-occurrent and due to nontraumatic subarachnoid hemorrhage (disorder) |
| 140881000119109 | Compression of brain co-occurrent and due to spontaneous cerebral hemorrhage (disorder) |
| 135801000119109 | Compression of brain due to focal lesion |
| 110030002 | Concussion injury of brain |
| 34663006 | Contusion of brain |
| 84170006 | Contusion of brain with open intracranial wound |
| 90768003 | Contusion of brain without open intracranial wound |
| 342751000119101 | Cortical blindness of left side of brain (disorder) |
| 342741000119103 | Cortical blindness of right side of brain (disorder) |
| 445166009 | Cystic degeneration of brain |
| 441460004 | Cysticercosis of brain |
| 52522001 | Degenerative brain disorder |
| 133301000119102 | Degenerative brain disorder caused by alcohol (disorder) |
| 276730002 | Dermoid cyst of brain |
| 262693007 | Diffuse brain injury |
| 210038008 | Focal brain injury |
| 429565004 | Germ cell tumor of the brain |
| 301764006 | Hematoma of brain |
| 209885000 | Hind brain contusion with open intracranial wound, with 1-24 hours loss of consciousness |
| 209884001 | Hind brain contusion with open intracranial wound, with less than 1 hour loss of consciousness |
| 209886004 | Hind brain contusion with open intracranial wound, with more than 24 hours loss of consciousness and return to pre-existing conscious level |
| 209887008 | Hind brain contusion with open intracranial wound, with more than 24 hours loss of consciousness without return to pre-existing conscious level |
| 209883007 | Hind brain contusion with open intracranial wound, with no loss of consciousness |
| 209900006 | Hind brain laceration with open intracranial wound |
| 209904002 | Hind brain laceration with open intracranial wound, with 1-24 hours loss of consciousness |
| 209903008 | Hind brain laceration with open intracranial wound, with less than 1 hour loss of consciousness |
| 209905001 | Hind brain laceration with open intracranial wound, with more than 24 hours loss of consciousness and return to pre-existing conscious level |
| 209906000 | Hind brain laceration with open intracranial wound, with more than 24 hours loss of consciousness without return to pre-existing conscious level |
| 209902003 | Hind brain laceration with open intracranial wound, with no loss of consciousness |
| 95659007 | Hindbrain hernia headache |
| 253203003 | Hypoplasia of brain gyri |
| 389088001 | Hypoxia of brain |
| 126944002 | Hypoxic-ischemic brain injury |
| 128614008 | Infectious disease of brain |
| 431266005 | Intraparenchymal hematoma of brain |
| 449020009 | Intraparenchymal hemorrhage of brain |
| 78914008 | Laceration of brain |
| 22819008 | Laceration of brain with open intracranial wound |
| 55702009 | Laceration of brain without open intracranial wound |
| 254941009 | Mixed glial tumor of brain |
| 204074000 | Multiple brain anomalies |
| 192926004 | Multiple sclerosis of the brainstem |
| 126952004 | Neoplasm of brain |
| 126961004 | Neoplasm of brain stem |
| 94767002 | Neoplasm of uncertain behavior of brain |
| 94766006 | Neoplasm of uncertain behavior of brain stem |
| 189488006 | Neoplasm of uncertain or unknown behavior of brain, Infratentorial |
| 189487001 | Neoplasm of uncertain or unknown behavior of brain, supratentorial |
| 281560004 | Neuroblastoma of brain |
| 254944001 | Neuronal and mixed neuronal - glial tumor of brain |
| 76011009 | Non-specific brain syndrome |
| 209881009 | Open hindbrain contusion |
| 126945001 | Perinatal anoxic-ischemic brain injury |
| 187080002 | Pheohyphomycotic brain abscess |
| 698837003 | Posttraumatic porencephalic cyst of brain (disorder) |
| 204032005 | Reduction deformities of brain |
| 127294003 | Traumatic AND/OR non-traumatic brain injury |
| 127295002 | Traumatic brain injury |
| 708728007 | Traumatic brain injury of unknown intent (disorder) |
| 127299008 | Traumatic brain injury with brief loss of consciousness |
| 127298000 | Traumatic brain injury with loss of consciousness |
| 450569000 | Traumatic brain injury with loss of consciousness one hour or more |
| 127300000 | Traumatic brain injury with moderate loss of consciousness |
| 127302008 | Traumatic brain injury with no loss of consciousness |
| 127301001 | Traumatic brain injury with prolonged loss of consciousness |
| 450551009 | Traumatic brain injury with prolonged loss of consciousness (more than 24 hours) and return to pre-existing conscious level |
| 450552002 | Traumatic brain injury with prolonged loss of consciousness (more than 24 hours) without return to pre-existing conscious level |
| 428089008 | Venous hemangioma of brain |

# APPENDIX 4: References

1. National Institute of Neurological Disorders and Stroke (NINDS) CDE project, Traumatic Brain Injury (TBI) CDEs (v2), https://www.commondataelements.ninds.nih.gov/TBI.aspx#tab=Data\_Standards
2. National Institute of Neurological Disorders and Stroke (NINDS) CDE project, Traumatic Brain Injury (TBI) CDEs (v2), Significant Medical History form (F0302\_ Significant Medical History.docx)
3. https://www.commondataelements.ninds.nih.gov/TBI.aspx#tab=Data\_Standards
4. National Institute of Neurological Disorders and Stroke (NINDS) CDE project, General CDEs, Medical History form (F0013Medical\_History.docx) https://www.commondataelements.ninds.nih.gov/General.aspx#tab=Data\_Standards
5. National Institute of Neurological Disorders and Stroke (NINDS) CDE project, Headache CDEs, Medical History form (F1355\_Medical\_and\_Family\_History\_of\_Headache\_Migraine.docx) https://www.commondataelements.ninds.nih.gov/Headache.aspx#tab=Data\_Standards
6. National Institute of Neurological Disorders and Stroke (NINDS) CDE project, Spinal Cord Injury (SCI), Medical History form (F1725\_Medical\_History) https://www.commondataelements.ninds.nih.gov/SCI.aspx#tab=Data\_Standards
7. John K. Yue, Mary J. Vassar, Hester F. Lingsma, Shelly R. Cooper, David O. Okonkwo, Alex B. Valadka, Wayne A. Gordon, Andrew I. R. Maas, Pratik Mukherjee, Esther L. Yuh, Ava M. Puccio, David M. Schnyer, Geoffrey T. Manley and TRACK-TBI Investigators including:, Scott S. Casey, Maxwell Cheong, Kristen Dams-O'Connor, Allison J. Hricik, Emily E. Knight, Edwin S. Kulubya, David K. Menon, Diane J. Morabito, Jennifer L. Pacheco, and Tuhin K. Sinha. Journal of Neurotrauma. October 2013, 30(22): 1831-1844. doi:10.1089/neu.2013.2970.
8. Kathryn E. Saatman, Ann-Christine Duhaime, Ross Bullock, Andrew I.R. Maas, Alex Valadka, and Geoffrey T. Manley. Journal of Neurotrauma. November 2010, 25(7): 719-738. doi:10.1089/neu.2008.0586.
9. Maas, Stocchetti, Bullock , Moderate and severe traumatic brain injury in adults, A review, The LANCET Neurology, Volume 7, Issue 8, August 2008, Pages 728–741, http://dx.doi.org/10.1016/S1474-4422(08)70164-9
10. Cantor J, Ashman T, Dams-O’Connor K, et al. Evaluation of the short-term executive plus intervention for executive dysfunction after traumatic brain injury: a randomized controlled trial with minimization. Arch Phys Med Rehabil. 2014;95(1):1-9.e3.
11. Maas et al, Standardizing Data Collection in Traumatic Brain Injury, J Neurotrauma. 2011 Feb; 28(2): 177–187. doi: 10.1089/neu.2010.1617
12. Hawryluk GW, Manley GT. Classification of traumatic brain injury: past, present, and future. Handb Clin Neurol. 2015;127:15-21.
13. Lingsma HF, Yue JK, Maas AI, Steyerberg EW, Manley GT; TRACK-TBI Investigators, Cooper SR, Dams-O'Connor K, Gordon WA, Menon DK, Mukherjee P, Okonkwo DO, Puccio AM, Schnyer DM, Valadka AB, Vassar MJ, Yuh EL. Outcome prediction after mild and complicated mild traumatic brain injury: external validation of existing models and identification of new predictors using the TRACK-TBI pilot study. J Neurotrauma. 2015 Jan 15;32(2):83-94.
14. Sherer M et al, Early cognitive status and productivity outcome after traumatic brain injury: Findings from the TBI Model Systems, Archives of Physical Medicine and Rehabilitation, Volume 83, Issue 2, February 2002, Pages 183–192
15. Pellman, Elliot J. M.D.; Powell, John W. Ph.D.; Viano, David C. Dr. med., Ph.D.; Casson, Ira R. M.D.; Tucker, Andrew M. M.D.; Feuer, Henry M.D.; Lovell, Mark Ph.D.; Waeckerle, Joseph F. M.D.; Robertson, Douglas W. M.D. Concussion in Professional Football: Epidemiological Features of Game Injuries and Review of the LiteraturePart 3. Neurosurgery: January 2004 - Volume 54 - Issue 1 - pp 81-96, doi: 10.1227/01.NEU.0000097267.54786.54
16. IMPACT: International Mission for Prognosis and Analysis of Clinical Trials in TBI, Medical History http://www.tbi-impact.org/cde/mod\_templates/T\_6.%20Medical%20History%209.1.pdf
17. CDISC Traumatic Brain Injury Therapeutic Area Data Standard User Guide v1 (Provisional), https://www.cdisc.org/traumatic-brain-injury-therapeutic-area
18. REPORT TO CONGRESS, Traumatic Brain Injury in the United States: Epidemiology and Rehabilitation, Submitted by the Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, Division of Unintentional Injury Prevention - <https://www.cdc.gov/traumaticbraininjury/pdf/tbi_report_to_congress_epi_and_rehab-a.pdf>
19. S. Harabangui et. Al. Experiments with Open-Domain Textual Question Answering, in proceedings of COLING-2000, Saarburkrn, Germany, pp 292-298, August 2000