



Summary of Core and Supplemental – Highly Recommended Recommendations: Headache CDEs

Start-up Resource – NINDS Headache CDE Recommendations

The National Institute of Neurological Disorders and Stroke (NINDS) and other Federal agencies and international organizations have the common mission of developing data standards for clinical research. Through the efforts of subject-specific working groups, topic-driven data elements have been created. The first set of Common Data Elements (CDEs) for Headache was developed in 2011. The Core and Supplemental – Highly Recommended data elements to be used by an investigator when beginning a research study in this disease/disorder are listed in this resource document. All other recommendations are listed on the website and should be considered based on study type.

Each CDE or instrument could be classified according to the definitions below:

General Core: A data element that is required for all NINDS funded studies.

Disease Core: A data element that collects essential information applicable to any disease-specific study, including all therapeutic areas. The NINDS and its appointed working groups assign the disease “Core” classification based on the current clinical research best practices. In each case, the disease Core CDEs are a small subset of the available CDEs, where it is anticipated that investigators will need to collect the disease Core CDEs on any type of study. These are required for all disease-specific studies.

Disease Supplemental - Highly Recommended: A data element which is essential based on certain conditions or study types in clinical research studies. In most cases, these have been used and validated in the disease area. These data elements are strongly recommended for the specified disease condition, study type or design.

Disease Supplemental: A data element which is commonly collected in clinical research studies. Use depends upon the study design, protocol or type of research involved. These are recommended, but not required, for studies.

Disease Exploratory: A data element that requires further validation, but may fill current gaps in the CDEs and/or substitute for an existing CDE once validation is complete. Such data elements show great promise, but require further validation before they are ready for prime-time use in clinical research studies. They are reasonable to use with the understanding that it has limited validation in the target group.



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<p>National Institute of Health (NIH) Resources: <i>The NINDS also strongly encourages researchers to use these NIH developed materials for NINDS-sponsored research, when appropriate. Utilization of these resources will enable greater consistency for NINDS-sponsored research studies. These tools are free of charge.</i></p>	<ul style="list-style-type: none"> • NIH Toolbox <ul style="list-style-type: none"> • Quality of Life in Neurological Disorders (Neuro-QOL) • Patient-Reported Outcomes Measurement Information System (PROMIS)
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Core CDEs for all NINDS Studies¹:

CDE Domain	CDE Name	CDE ID	Classification	Study Type
Demographics	Birth date	C00007	CORE	All studies
Demographics	Ethnicity USA category	C00020	CORE	All studies
Demographics	Race USA category	C00030	CORE	All studies
Demographics	Gender Type	C00035	CORE	All studies
General Health History	Medical history condition text	C00322	CORE	All studies
General Health History	Medical history condition SNOMED CT code	C00313	CORE	All studies

Core CDEs for Headache Studies:

CDE Domain	CDE Name	CDE ID
Vital Signs and Other Body Measures	Height measurement	C01522
Vital Signs and Other Body Measures	Weight measurement	C01541

¹ Note: Education year count C00015 is no longer a general Core CDE



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Supplemental – Highly Recommended for Headache Studies:

Domain; Sub-Domain	Data Element	CDE ID
Participant/Subject Characteristics; Demographics	Age value	C00008
Participant/Subject Characteristics; Social Status	Education level USA type	C00012
Participant/Subject Characteristics; Social Status	Employment status	C00204
Participant/Subject Characteristics; Social Status	Family income range	C00205
Participant/Subject Characteristics; Social Status	Family income supported persons count	C00206
Participant/Subject Characteristics; Social Status	Marital or partner status	C00207
Participant/Subject Characteristics; Social Status	Military USA service branch type	C00208
Participant/Subject Characteristics; Social Status	Military combat zone deployment number	C00209
Participant/Subject Characteristics; Social Status	Military combat status	C00210
Participant/Subject Characteristics; Social Status	Living with persons count	C00214
Participant/Subject Characteristics; Social Status	Living with person relationship type	C00215
Participant/Subject Characteristics; Social Status	Military USA rank category	C00220
Participant/Subject Characteristics; Social Status	Military service status	C00221
Participant/Subject Characteristics; Social Status	Job classification category	C00222
Participant/Subject Characteristics; Social Status	Health insurance type	C00226
Participant/Subject Characteristics; Social Status	School repeat grade indicator	C14117
Participant/Subject Characteristics; Social Status	Student course load status	C15986
Participant/Subject Characteristics; Social Status	Employment weekly hour count	C15987
Participant/Subject Characteristics; Social Status	Employment paid job count	C15988
Participant/Subject Characteristics; Social Status	Unemployed reason	C15989



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Domain; Sub-Domain	Data Element	CDE ID
Participant/Subject Characteristics; Social Status	Military non-combat zone deployment number	C15990
Participant/Subject Characteristics; Social Status	Deployment most recent start date and time	C15991
Participant/Subject Characteristics; Social Status	Deployment most recent end date and time	C15992
Participant/Subject Characteristics; Social Status	Dependent children number	C15993
Participant/Subject Characteristics; Social Status	Dependent children living in household number	C15994
Participant/Subject Characteristics; Social Status	Household wage earners number	C15995
Participant/Subject Characteristics; Social Status	Data source	C08147
Participant/Subject Characteristics; Social Status	Adopted indicator	C10813
Participant/Subject History and Family History; General Health History	Relative first degree total count	C15997
Participant/Subject History and Family History; General Health History	Relative first degree live count	C15998
Participant/Subject History and Family History; General Health History	Relative first degree decease count	C15999
Participant/Subject History and Family History; General Health History	Relative first degree unknown count	C16000
Participant/Subject History and Family History; General Health History	Relative second degree total count	C16001
Participant/Subject History and Family History; General Health History	Relative second degree live count	C16002
Participant/Subject History and Family History; General Health History	Relative second degree decease count	C16003
Participant/Subject History and Family History; General Health History	Relative second-degree unknown count	C16004



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Domain; Sub-Domain	Data Element	CDE ID
Participant/Subject History and Family History; General Health History	Data collected date and time	C06005
Participant/Subject History and Family History; General Health History	Pregnant ever indicator	C10556
Participant/Subject History and Family History; General Health History	Birth control method type	C10981
Participant/Subject History and Family History; General Health History	Gravida maternal value	C11065
Participant/Subject History and Family History; General Health History	Pregnancy indicator	C15624
Participant/Subject History and Family History; General Health History	Birth control indicator	C16008
Participant/Subject History and Family History; General Health History	Birth control last used date and time	C16009
Participant/Subject History and Family History; General Health History	Pregnancy confirmed date and time	C16011
Participant/Subject History and Family History; General Health History	Pregnancy estimated delivery date ultrasound based indicator	C16013
Participant/Subject History and Family History; General Health History	Pregnancy prenatal testing performed indicator	C16014
Participant/Subject History and Family History; General Health History	Prenatal testing type	C16015
Participant/Subject History and Family History; General Health History	Prenatal testing date and time	C16016
Participant/Subject History and Family History; General Health History	Prenatal testing result	C16017



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Domain; Sub-Domain	Data Element	CDE ID
Participant/Subject History and Family History; General Health History	Pregnancy complication indicator	C16018
Participant/Subject History and Family History; General Health History	Pregnancy infection illness indicator	C16020
Participant/Subject History and Family History; General Health History	Pregnancy prior history births full-term count	C16022
Participant/Subject History and Family History; General Health History	Pregnancy prior history births pre-term count	C16023
Participant/Subject History and Family History; General Health History	Pregnancy prior history birth defect indicator	C16024
Participant/Subject History and Family History; General Health History	Pregnancy prior history loss indicator	C16026
Participant/Subject History and Family History; General Health History	Pregnancy prior history loss week count	C16027
Participant/Subject History and Family History; General Health History	Pregnancy prior history toxic exposure type	C16028
Participant/Subject History and Family History; General Health History	Pregnancy estimated delivery date and time	C16173
Participant/Subject History and Family History; General Health History	Menstrual period last date	C16175
Participant/Subject History and Family History; General Health History	Delivery or pregnancy termination last date and time	C10558
Participant/Subject History and Family History; General Health History	Delivery mode type	C11078
Participant/Subject History and Family History; General Health History	Neonate delivery route type	C11079



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Domain; Sub-Domain	Data Element	CDE ID
Participant/Subject History and Family History; General Health History	Delivery caesarean timing status	C11081
Participant/Subject History and Family History; General Health History	Pregnancy most recent live born infant indicator	C16037
Participant/Subject History and Family History; General Health History	Pregnancy fetus normal indicator	C16040
Participant/Subject History and Family History; General Health History	Delivery induced reason	C16042
Participant/Subject History and Family History; General Health History	Delivery cesarean section reason	C16044
Participant/Subject History and Family History; General Health History	Pregnancy labor delivery complication indicator	C16046
Participant/Subject History and Family History; General Health History	Tocolytic agents required during preterm labor indicator	C16048
Participant/Subject History and Family History; General Health History	Birth child date and time	C16049
Participant/Subject History and Family History; General Health History	Phenotypic sex child type	C16050
Participant/Subject History and Family History; General Health History	Birth weight child value	C16051
Participant/Subject History and Family History; General Health History	Birth length child value	C16053
Participant/Subject History and Family History; General Health History	Full term delivery child indicator	C16055
Participant/Subject History and Family History; General Health History	Gestational age child value	C16056



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Domain; Sub-Domain	Data Element	CDE ID
Participant/Subject History and Family History; General Health History	Activity pulse grimace appearance respiration five minute child score	C16057
Participant/Subject History and Family History; General Health History	Activity pulse grimace appearance respiration ten minute child score	C16058
Participant/Subject History and Family History; General Health History	Weight delivery mother measurement	C16059
Participant/Subject History and Family History; General Health History	Weight delivery mother unit of measure	C16060
Participant/Subject History and Family History; General Health History	Pregnancy fetal diagnostic test performed indicator	C16062
Participant/Subject History and Family History; General Health History	Pregnancy fetal diagnostic test date	C16063
Participant/Subject History and Family History; General Health History	Pregnancy fetal diagnostic test result	C16064
Participant/Subject History and Family History; General Health History	Congenital anomaly child indicator	C16065
Participant/Subject History and Family History; General Health History	Newborn complication child indicator	C16067
Participant/Subject History and Family History; General Health History	Placenta umbilical cord abnormality indicator	C16069
Participant/Subject History and Family History; General Health History	Pregnancy outcome type	C16169
Participant/Subject History and Family History; General Health History	Delivery induced reason other text	C18617
Disease/Injury Related Events; History of Disease/Injury Event	Headache migraine type	C16005



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Domain; Sub-Domain	Data Element	CDE ID
Disease/Injury Related Events; History of Disease/Injury Event	Headache migraine diagnosis indicator	C16010
Disease/Injury Related Events; History of Disease/Injury Event	Headache history indicator	C15936
Disease/Injury Related Events; History of Disease/Injury Event	Headache typical severity type	C15937
Disease/Injury Related Events; History of Disease/Injury Event	Headache typical level activities affected result	C15939
Disease/Injury Related Events; History of Disease/Injury Event	Headache typical associate symptom type	C15940
Disease/Injury Related Events; History of Disease/Injury Event	Headache symptom frequency	C15941
Disease/Injury Related Events; History of Disease/Injury Event	Headache month average frequency	C15942
Disease/Injury Related Events; Classification	Vision (aura) typical symptom type	C15946
Disease/Injury Related Events; Classification	Skin sensation typical indicator	C15947
Disease/Injury Related Events; Classification	Skin sensation frequency	C15948
Disease/Injury Related Events; Classification	Headache typical anatomic site	C15949
Disease/Injury Related Events; Classification	Headache typical pain type	C15950
Disease/Injury Related Events; Classification	Headache short treatment duration	C15951



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Domain; Sub-Domain	Data Element	CDE ID
Disease/Injury Related Events; Classification	Headache long treatment duration	C15952
Disease/Injury Related Events; Classification	Headache average treatment duration	C15953
Disease/Injury Related Events; Classification	Headache shortest untreated duration	C15954
Disease/Injury Related Events; Classification	Headache longest untreated duration	C15955
Disease/Injury Related Events; Classification	Headache average untreated duration	C15956
Disease/Injury Related Events; Classification	Headache frequency	C15958
Disease/Injury Related Events; Classification	Headache pain walk up stair typical indicator	C15960
Disease/Injury Related Events; Classification	Headache worse during activity indicator	C15961
Disease/Injury Related Events; Classification	Headache affect activity level indicator	C15962
Disease/Injury Related Events; Classification	Headache school function level percentage value	C15963
Disease/Injury Related Events; Classification	Headache play function level percentage value	C15964
Assessments and Examinations; Vital Signs and Other Body Measures	Blood pressure diastolic measurement	C01507
Assessments and Examinations; Vital Signs and Other Body Measures	Height measurement method type	C01513



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Domain; Sub-Domain	Data Element	CDE ID
Assessments and Examinations; Vital Signs and Other Body Measures	Height measurement	C01522
Assessments and Examinations; Vital Signs and Other Body Measures	Weight measurement	C01541
Assessments and Examinations; Vital Signs and Other Body Measures	Weight measurement method type	C01546
Assessments and Examinations; Vital Signs and Other Body Measures	Blood pressure measurement position type	C01553
Assessments and Examinations; Vital Signs and Other Body Measures	Blood pressure systolic measurement	C01565
Assessments and Examinations; Vital Signs and Other Body Measures	Weight unit of measure	C01581
Assessments and Examinations; Vital Signs and Other Body Measures	Height unit of measure	C01582
Assessments and Examinations; Vital Signs and Other Body Measures	Weight percentile value	C15900
Assessments and Examinations; Vital Signs and Other Body Measures	Height percentile value	C15901
Assessments and Examinations; Vital Signs and Other Body Measures	Weight to height ratio value	C15902
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Lab specimen collection date and time	C01701
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Food last consumed date and time	C10821



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Domain; Sub-Domain	Data Element	CDE ID
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Last headache current day elapse time	C15596
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Last headache sample collection elapse time	C15599
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Headache severity prior sample collection score	C15604
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Medication history change indicator	C15607
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Premenopausal indicator	C15618
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Menstrual cycle day collection time value	C15621
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Pregnancy gestational week value	C15627
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Postpartum indicator	C15629



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Domain; Sub-Domain	Data Element	CDE ID
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Postpartum day week value	C15630
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Premenarchal indicator	C15632
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Gene type	C10844
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Gene screened indicator	C10845
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Gene mutation indicator	C10846
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Genetic testing performed indicator	C15520
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Headache gene present indicator	C15522
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Gene mutation type	C15539



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Domain; Sub-Domain	Data Element	CDE ID
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Gene nucleotide change name	C15545
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Gene amino acid change name	C15549
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Gene unclassified variant shown indicator	C15553
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Gene detection method type	C15557
Treatment/Intervention Data; Drugs	Medication prior or concomitant use indicator	C02002
Treatment/Intervention Data; Drugs	Medication prior or concomitant ongoing indicator	C02003
Treatment/Intervention Data; Drugs	Medication prior or concomitant dose	C02006
Treatment/Intervention Data; Drugs	Medication prior or concomitant end date and time	C02008
Treatment/Intervention Data; Drugs	Medication prior or concomitant dose frequency	C02011
Treatment/Intervention Data; Drugs	Medication prior or concomitant dose unit of measure UCUM code	C02013
Treatment/Intervention Data; Drugs	Medication prior or concomitant name	C02014



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Domain; Sub-Domain	Data Element	CDE ID
Treatment/Intervention Data; Drugs	Medication prior or concomitant route type	C02015
Treatment/Intervention Data; Drugs	Medication prior or concomitant start date and time	C02016
Treatment/Intervention Data; Drugs	Medication prior or concomitant dose unit of measure	C02022
Treatment/Intervention Data; Drugs	Medication prior or concomitant indication text	C02024
Treatment/Intervention Data; Drugs	Adverse event track number	C16029
Treatment/Intervention Data; Drugs	Headache pain medication after study drug indicator	C16211
Outcomes and End PointsPatient Reported Outcomes	Headache retire bed indicator	C15893
Outcomes and End PointsPatient Reported Outcomes	Headache associated symptom type	C15897
Outcomes and End PointsPatient Reported Outcomes	Headache worst pain anatomic site	C15899
Outcomes and End PointsPatient Reported Outcomes	Headache or migraine medication taken type	C15969
Outcomes and End PointsPatient Reported Outcomes	Headache warning symptom indicator	C15971
Outcomes and End PointsPatient Reported Outcomes	Headache aura symptom type	C15972
Outcomes and End PointsPatient Reported Outcomes	Headache aura symptom onset range	C15973



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Domain; Sub-Domain	Data Element	CDE ID
Outcomes and End PointsPatient Reported Outcomes	Headache post initial study medication time interval value	C15975
Outcomes and End PointsPatient Reported Outcomes	Headache post initial study medication date and time	C15976
Outcomes and End PointsPatient Reported Outcomes	Headache end date and time	C15977
Outcomes and End PointsPatient Reported Outcomes	Headache re-start date and time	C15978
Outcomes and End PointsPatient Reported Outcomes	Headache re-start end date and time	C15979
Outcomes and End PointsPatient Reported Outcomes	Headache affected activity type	C15980
Outcomes and End PointsPatient Reported Outcomes	Headache pain medication time AM PM indicator	C18028

General Core for all Studies:

Investigators should review the FDA’s ["Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials"](#) for the most up-to-date information about suicidal ideation and behavior. One scale that FDA suggests is the Columbia Suicide Severity Rating Scale (C-SSRS) (available at [Columbia Suicide Severity Rating Scale Website](#)).

Core Instruments for Headache Studies:

1. Patient diagnosis with the [International Classification of Headache Disorders, 3rd edition](#) (or latest version) criteria
2. Impact assessment with one of the following:
 - a. [Functional Disability Inventory \(FDI\)-Child and Adolescent Form](#)
 - b. [Functional Disability Inventory \(FDI\)-Parent Form](#)
 - c. [Headache Impact Test-6 \(HIT-6\)](#)
 - d. [Migraine Specific Quality of Life Questionnaire \(MSQoL\)](#)



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- e. [Pediatric Migraine Disability Assessment \(PedMIDAS\)](#)
3. [Headache Diary](#) – Headache frequency or characteristics assessment through calendar or diary (includes CDE indicator for medication use)

For the complete list of NINDS CDE recommendations for Headache, please see the [NINDS CDE website](#).