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.

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

National Institute of Health (NIH) Resources: *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.*	• **NIH Toolbox** • **Quality of Life in Neurological Disorders (Neuro-QOL)** • **Patient-Reported Outcomes Measurement Information System (PROMIS)**

Core CDEs for all NINDS Studies[1]:

Domain; Subdomain	CDE Name	CDE ID	Study Type
Participant Characteristics; Demographics	Birth date	C00007	All studies
Participant Characteristics; Demographics	Ethnicity USA category	C00020	All studies
Participant Characteristics; Demographics	Race USA category	C00030	All studies
Participant Characteristics; Demographics	Birth sex assigned type	C58676	All studies
Participant Characteristics; Demographics	Gender identity type	C58677	All studies
Participant History and Family History; General Health History	Medical history condition text	C00322	All studies
Participant History and Family History; General Health History	Medical history condition SNOMED CT code	C00313	All studies

Core CDEs for Headache Studies:

Domain; Subdomain	CDE Name	CDE ID
Participant Characteristics; Demographics	Assessment performed date	C19500

---

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

Summary of Core and Supplemental – Highly Recommended Recommendations:

Headache CDEs

Domain; Subdomain	CDE Name	CDE ID
Participant Characteristics; Social Status	Education level USA type	C00012
Participant Characteristics; Social Status	Education year count	C00015
Participant Characteristics; Social Status	Marital or partner status	C00207
Participant Characteristics; Social Status	Employment current status	C00204
Assessments and Examination; Vital Signs and Other Body Measures	Vital signs date and time	C01519
Assessments and Examinations; Vital Signs and Other Body Measures	Blood pressure systolic measurement	C01565
Assessments and Examinations; Vital Signs and Other Body Measures	Blood pressure diastolic measurement	C01507
Assessments and Examinations; Vital Signs and Other Body Measures	Weight measurement	C01541
Assessments and Examination; Vital Signs and Other Body Measures	Weight unit of measure	C01581
Assessments and Examinations; Vital Signs and Other Body Measures	Height measurement	C01522

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

Domain; Subdomain	CDE Name	CDE ID
Assessments and Examinations; Vital Signs and Other Body Measures	Height unit of measure	C01582
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Headache 28 day prior to sample collection frequency	C56059

Supplemental-Highly Recommended CDEs for Headache studies:

Domain; Subdomain	CDE Name	CDE ID
Participant Characteristics; Demographics	Education year count	C00015
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Premenopausal indicator	C15618
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Menopause indicator	C16174
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Post-menopausal indicator	C16177
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Specimen collected for biomarker indicator	C56093
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Biomarker specimen type	C56102
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Specimen centrifugation performed indicator	C56123
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Specimen centrifugation temperature value	C55004

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

Domain; Subdomain	CDE Name	CDE ID
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Other processing method performed indicator	C56127
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Specimen frozen indicator	C56129
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Original specimen repeated refrozen rethawed indicator	C56130
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Frozen aliquot volume value	C56131
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Frozen aliquot volume unit of measure	C56133
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Specimen freezing time	C56134
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Specimen storage temperature value	C55009
Outcomes and End Points; Patient Reported Outcomes	Condition diary date and time	C10626
Outcomes and End Points; Patient Reported Outcomes	Diary day headache indicator	C15966
Outcomes and End Points; Patient Reported Outcomes	Diary day migraine indicator	C15967
Outcomes and End Points; Patient Reported Outcomes	Headache start date and time	C56777
Outcomes and End Points; Patient Reported Outcomes	Headache end date and time	C15977
Outcomes and End Points; Patient Reported Outcomes	Headache migraine onset time	C56043
Outcomes and End Points; Patient Reported Outcomes	Headache migraine end time	C56044
Outcomes and End Points; Patient Reported Outcomes	Headache or migraine medication taken type	C15969
Outcomes and End Points; Patient Reported Outcomes	Headache or migraine medication taken other text	C19034
Outcomes and End Points; Patient Reported Outcomes	Pain present eleven point intensity scale	C22804
Outcomes and End Points; Patient Reported Outcomes	Headache severity scale	C56042

Summary of Core and Supplemental – Highly Recommended Recommendations:

Headache CDEs

Domain; Subdomain	CDE Name	CDE ID
Outcomes and End Points; Patient Reported Outcomes	Headache typical severity type	C15937
Outcomes and End Points; Patient Reported Outcomes	Headache typical pain intensity scale	C15917
Outcomes and End Points; Patient Reported Outcomes	Headache typical pain type	C15950
Outcomes and End Points; Patient Reported Outcomes	Headache typical pain other text	C19032
Outcomes and End Points; Patient Reported Outcomes	Laterality type	C02411
Outcomes and End Points; Patient Reported Outcomes	Headache worst pain anatomic site	C15899
Outcomes and End Points; Patient Reported Outcomes	Headache pain hurt most eye type	C56778
Outcomes and End Points; Patient Reported Outcomes	Headache worst pain anatomic other text	C19027
Outcomes and End Points; Patient Reported Outcomes	Headache sound aggravate indicator	C56779
Outcomes and End Points; Patient Reported Outcomes	Migraine headache light indicator	C53077
Outcomes and End Points; Patient Reported Outcomes	Headache worse during activity indicator	C15961
Outcomes and End Points; Patient Reported Outcomes	Headache warning symptom indicator	C15971
Outcomes and End Points; Patient Reported Outcomes	Headache premonitory symptom type	C56785
Outcomes and End Points; Patient Reported Outcomes	Headache aura symptom type	C15972
Outcomes and End Points; Patient Reported Outcomes	Headache reduce activity level indicator	C56780
Outcomes and End Points; Patient Reported Outcomes	Headache typical level activities affected result	C15939
Outcomes and End Points; Patient Reported Outcomes	Headache post initial study medication time interval	C15975
Outcomes and End Points; Patient Reported Outcomes	Headache post initial study medication date and time	C15976
Outcomes and End Points; Patient Reported Outcomes	Headache associated symptom type	C15897
Outcomes and End Points; Patient Reported Outcomes	Headache retire bed indicator	C15893
Outcomes and End Points; Patient Reported Outcomes	Headache re-start date and time	C15978
Outcomes and End Points; Patient Reported Outcomes	Headache re-start end date and time	C15979
Outcomes and End Points; Patient Reported Outcomes	Headache re-start pain medication indicator	C56781
Outcomes and End Points; Patient Reported Outcomes	Headache re-start medication taken type	C56782

 Summary of Core and Supplemental – Highly Recommended Recommendations:

Headache CDEs

Domain; Subdomain	CDE Name	CDE ID
Outcomes and End Points; Patient Reported Outcomes	Headache re-start medication taken other text	C56784
Outcomes and End Points; Patient Reported Outcomes	Headache re-start medication taken time	C56783
Outcomes and End Points; Patient Reported Outcomes	Headache affect activity level indicator	C15962
Outcomes and End Points; Patient Reported Outcomes	Headache affected activity type	C15980

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).

Headache Core Instruments: The International Classification of Headache Disorders - III (*ICHD-3*) is recommended for use in all Headache studies.

Headache Supplemental Highly Recommended Instruments:

1. Headache Impact Test-6 (HIT-6)
2. ID Migraine Screener
3. Migraine Disability Assessment Test (MIDAS) *OR* Pediatric Migraine Disability Assessment Questionnaire (PedMIDAS)
4. Migraine Specific Quality of Life Questionnaire (MsQoL v2.1)
5. Generalized Anxiety Disorder (GAD-7)
6. Patient Health Questionnaire-4 (PHQ-4) *OR* Patient Health Questionnaire-9 (PHQ-9) Depression Scale

For the complete list of NINDS CDE recommendations for Headache, please see the NINDS CDE website.