NINDS Common Data Elements
Harmonizing information. Streamlining research.

Headache v2.0 NINDS CDE Project

Subgroup in Headache: Biomarkers
Completed by: B. Lee Peterlin (Co-Chair) and Michael Harrington (Co-Chair)

Please answer the following questions below.

1. **Approach for selection of elements** (*How did you go about drafting the recommendations and/or reviewing the current tools/instruments, and did you have any criteria for selection and classification?)*

   The group drafted their recommendations by participating in group discussion, debate, and lastly consensus.

2. **Differential application to types of Headache** *(Do the instruments/elements you recommended differ between the types of Headache?)*

   There will be some slight differences but largely no.

3. **Recommendations Summary Table:**

Instrument / Scale / CRF Name *Name and acronym of the instrument/measure that is recommended for inclusion in the CDEs*	**Domain**	**Sub-domain**	**Classification** (e.g., Core, Supplemental - Highly Recommended, Supplemental, Exploratory)
Medical and Family History CRF	Participant History and Family History	General Health History	Supplemental.
DNA Elements CRF	Assessments and Examinations	Laboratory Tests and Biospecimens/Biomarkers	Supplemental
Specimen Collection and Processing CRF	Assessments and Examinations	Laboratory Tests and Biospecimens/Biomarkers	Classifications vary: Core: 28-day headache days frequency

Instrument / Scale / CRF Name *Name and acronym of the instrument/measure that is recommended for inclusion in the CDEs*	**Domain**	**Sub-domain**	**Classification** (e.g., Core, Supplemental - Highly Recommended, Supplemental, Exploratory)
			prior to sample collection; Supplemental - Highly Recommended - Menopausal status; specimen collected for biomarkers; date and time of fluid intake; type of specimen was collected; centrifugation performed; Temperature of centrifugation; specimen frozen; specimen repeatedly re-frozen or re-thawed; Frozen aliquot volume; time of specimen freezing; Storage temperature Exploratory: Date and time of assay; sensitivity and specificity; upper and lower limit of detection of assay; intra assay and inter assay variability; Results of assay; length of time participant headache free; Specimen collection date and time; Time at onset of first headache following specimen obtained; Time of end of first headache; Type of headache; treatment for this headache Remaining CDEs are Supplemental.

4. **Comparison to other Headache standards** *(Are there any notable similarities/differences in the CDE recommendations as compared with other standards?)*

   The working group's recommendations are geared specifically to headache disorders.

5. **Issues unique to Headache** *(Were there any issues encountered when developing the CDE standards which are unique to Headache or which highlight a unique concern about Headache data collection?*

   One unique issue was sample collection timing in relationship to headache.

6. **Unmet needs; unanswered questions** *(What unmet need / unanswered questions were identified via the CDE process in Headache? What areas are in need of further research and development?)*

   The group feels confident these are a strong platform to be able to grow as new questions unfold.