



Developing Common Data Elements (CDEs) for Headache Clinical Research: A National Institute of Neurological Disorders and Stroke (NINDS), NIH Initiative

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Background

To reduce study start-up time, assist investigators conducting clinical studies and increase data sharing throughout the scientific community, the NINDS embarked on an initiative to create common data elements (CDEs) for neuroscience clinical research and worked with headache experts to develop disease-specific CDEs. To develop the Headache CDEs, a Working Group composed of five subgroups was formed to define elements in: 1. Demographics and Epidemiology; 2. Genetics; 3. Imaging and Neurophysiological Measures; 4. Acute Therapies; and 5. Preventive Therapies and Approaches. The Headache CDE Working Group finished development in December 2011 and Version 1.0 of the Headache CDEs was published on the NINDS CDE Web site (<http://www.commondataelements.ninds.nih.gov/>) for public use in May 2012.

CDE Set	Version 1.0 Published on Web site	Number of CDEs	Number of CRFs and Instruments/ Scales
Critical core/ General	Jun. 2006	181	23
Spinal cord injury (SCI)	Apr. 2010	642	15
Traumatic brain injury (TBI)	Apr. 2010	756	81
Epilepsy	Oct. 2010	655	42
Stroke	Dec. 2010	1130	54
Parkinson's disease (PD)	Feb. 2011	1151	63
Congenital muscular dystrophy (CMD)	Jun. 2011	579	30
Friedrich's ataxia (FA)	Sep. 2011	397	24
Amyotrophic lateral sclerosis (ALS)	Jan. 2012	757	70
Multiple sclerosis (MS)	Apr. 2012	484	72
Huntington's disease (HD)	May 2012	802	67
Headache	May 2012	583	58
TOTAL		8117	599

Above: The table summarizes the current contents of the Web site. The neurological clinical research community and NINDS have created Version 1.0 of 11 disease-specific CDEs and the General CDEs. These 12 CDE packages are currently available on the NINDS CDE Web site.

CDE Development

The CDE development process included the following steps:

- Identify domestic and international headache clinical research experts
- Utilize a secure SharePoint Web site to review existing materials (e.g., study case report forms [CRFs], publications, etc.), and newly created draft documents
- Meet via teleconference to develop a first draft of standardized CDE recommendations from the subgroups (May-December 2011)
- Vet draft recommendations across the Headache Working Group (January-February 2012)
- Release recommendations to the research community for public comment (February-March 2012)
- Review public comments and update the CDEs prior to publishing Version 1.0 on the NINDS CDE Web site (May 2012)

Results

Version 1.0 of the Headache CDEs includes:

- Catalog of **583 CDEs** with detailed specifications for each element.
- Library of **30 customizable CRF templates**.
- List of **28 standardized instruments** with explanations of when each instrument is recommended for use.

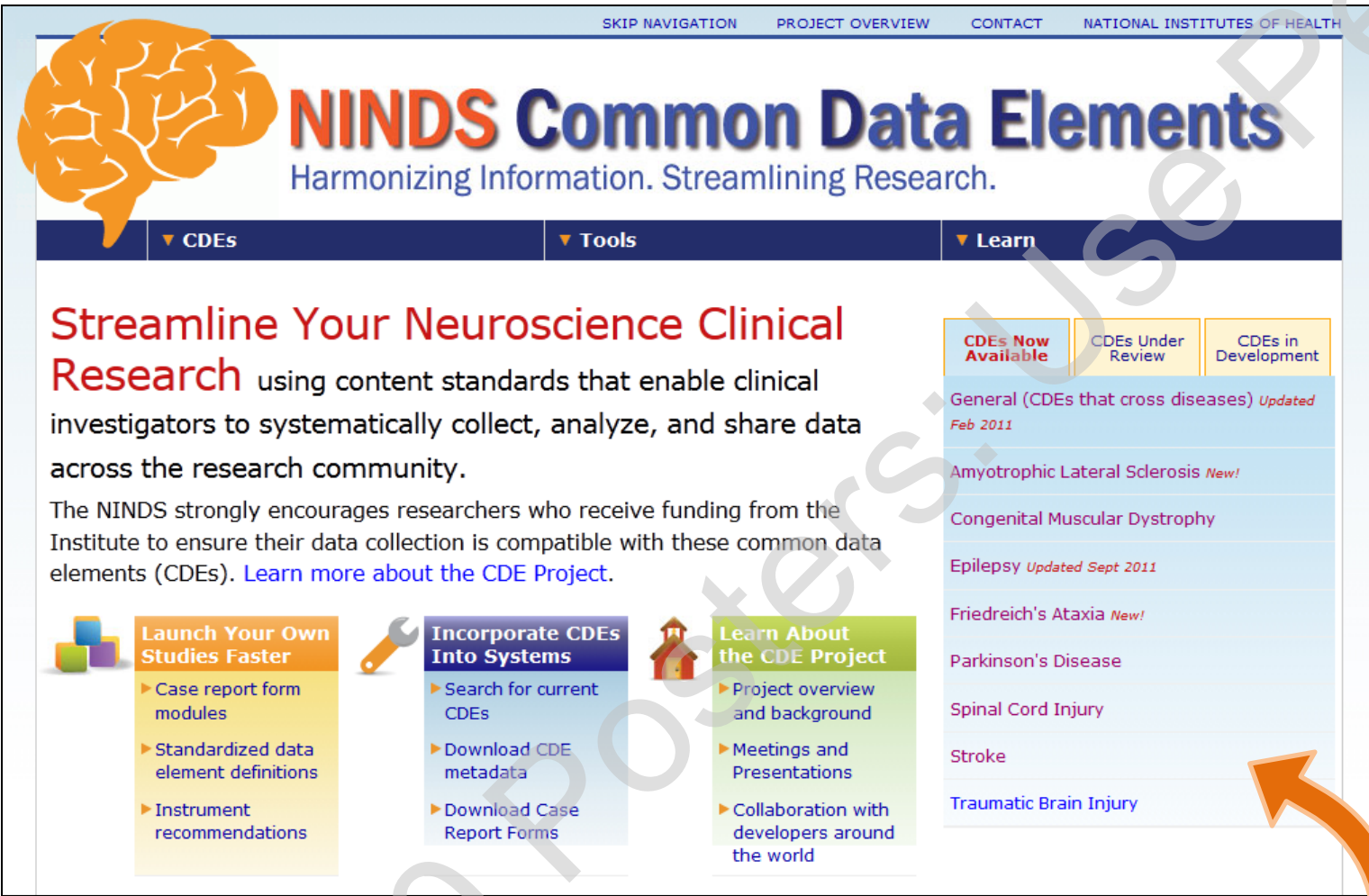
The Headache CDEs are freely accessible on the NINDS CDE Web site:

www.commondataelements.ninds.nih.gov

Also, of note:

- Training is available to research team members interested in using the Headache CDEs.
- The NINDS has future plans to review and update the Headache CDEs annually through an Oversight Committee.

Headache CDE Products

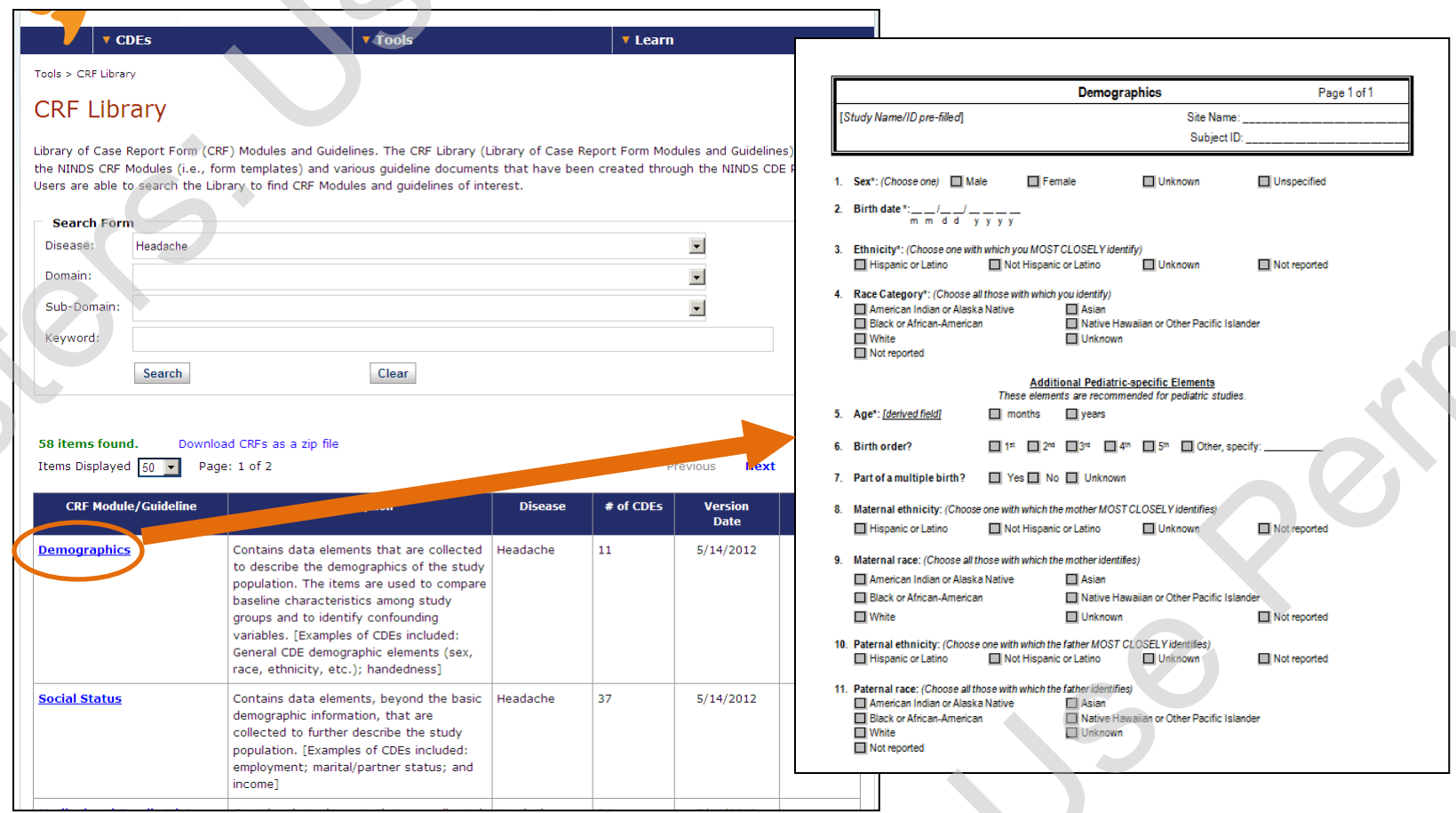
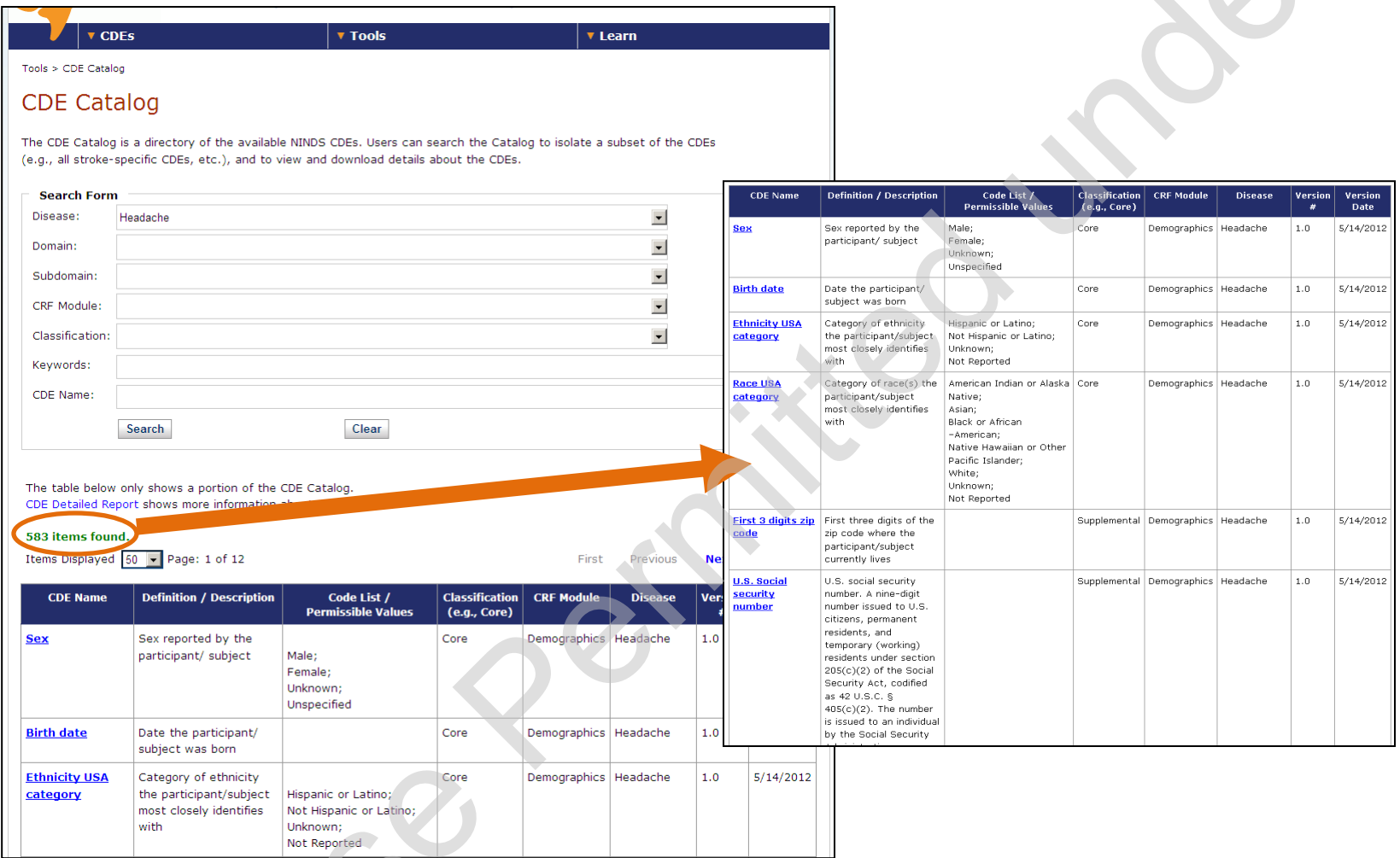


Above: The Home page of the Web site. The easiest way to access the Headache CDEs is by selecting 'Headache' from the right-hand 'CDEs Now Available' menu or from the 'CDEs' dropdown immediately beneath the title bar.



Above: The Headache page of the Web site includes all of the Headache CDEs, including template CRFs and detailed reports that define the CDEs.

Below: The 'CDE Catalog' and 'CRF Library' tools allow users to search for all Headache CDEs and CRFs, respectively and to download their search



Conclusion

The Headache CDEs (Version 1.0) have been developed and will be refined to maximize their utility in accelerating headache research based on feedback and periodic review. The NINDS strongly encourages investigators conducting headache clinical studies to use the Headache CDEs and to submit their comments and experiences. This feedback will be crucial to maintaining and improving the Headache CDEs over time. Feedback can be submitted through the Web site or by email (NINDSCommonData@kai-research.com or odenkirj@ninds.nih.gov).

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