

Common Data Elements Project



Harmonizing information. Streamlining research.



NINDS Common
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What is the CDE Project?

The National Institute of Neurological Disorders and Stroke (NINDS), part of the National Institutes of Health (NIH), is the nation's leading funder of clinical studies of the brain and nervous system. To harmonize data collected from clinical studies, the NINDS Office of Clinical Research is spearheading a project to develop common data elements (CDE) in neuroscience.

The use of CDEs is expected to reduce study start-up times and accelerate data sharing among clinical investigators. Central to the project is the identification of common definitions and the standardization of case report forms and other instruments. The CDE project will develop uniform formats by which clinical data can be systematically collected, analyzed and shared across the research community.



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What CDEs are being developed?

NINDS first developed a set of general CDEs commonly collected in all clinical studies regardless of the type of study or therapeutic area. Examples include medical history data; scores on neurological assessments; demographic information (e.g., age, race, ethnicity and educational level); and details about medications used by patients throughout a study.

In addition to these core elements, NINDS is also developing separate sets of CDEs tailored to research on specific diseases or disorders. Currently, the project has focused on the following areas:

- Spinal cord injury (SCI)
- Traumatic brain injury (TBI)
- Epilepsy
- Stroke
- Parkinson's disease (PD)
- Frontotemporal dementia (FTD)
- Muscular dystrophy
- Huntington's disease (HD)
- Amyotrophic lateral sclerosis (ALS)
- Headache
- Other

NINDS will continue to convene working groups to address CDEs for other neurological diseases as needed.

How will CDEs help clinical investigators?

The CDE project is a resource to help clinical investigators stop reinventing the wheel as they launch new studies. The use of CDEs across clinical neuroscience will help:

- Reduce the time and cost needed to develop data collection tools
- Promote data collection in a consistent manner
- Improve data quality
- Facilitate data sharing
- Improve opportunities for meta-analyses and comparison of results from different studies
- Increase the availability of data for the planning and design of new trials

The use of CDEs is not a requirement currently, but researchers who receive funding from NINDS must ensure that their data collection is compatible with the CDE project. In addition, CDEs do not include all variables that clinical investigators may need to collect in a particular study.

What groups are collaborating with NINDS?

For more than a year, NINDS has conducted working groups representing expertise in different areas of neuroscience addressing core and disease-specific elements. Participants included investigators from leading academic and government research centers.

For example, in developing CDEs for traumatic brain injury research NINDS collaborated with the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury (DCoE), the Department of Veterans Affairs (VA), the Defense and Veterans Brain Injury Center (DVBIC), and the National Institute on Disability and Rehabilitation Research (NIDRR).

NINDS recognizes that the best way to ensure CDEs remain current is to revise and extend the project based on feedback from the neurological community according to changes and advances in the clinical research landscape.

What is the website for the CDE project?

www.commondataelements.ninds.nih.gov

The site includes neurology data standards, an overview of the development of the data standards for each of the disorders currently in the system, references and acknowledgements of the people who have participated in the development, and an opportunity to make a comment or query the CDE teams. NINDS will continue to update the site with additional CDE materials, data dictionaries, new forms and other updates.

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