



National Institute of
Neurological Disorders
and Stroke

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NINDS Common
Data
Elements
Harmonizing information. Streamlining research.

NINDS Common Data Elements

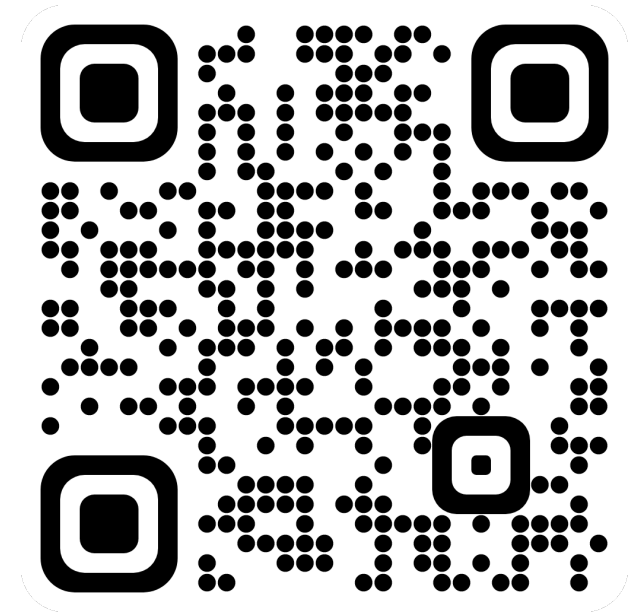
Challenges in Pediatric Neuroscience Research Webinar Series

November 3, 2022

■ NINDS CDE Program Director

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■ NINDS CDE NINDS CDE Website

<http://www.commondataelements.ninds.nih.gov>

Acknowledgements

- Working Group members
- Collaborators
- NINDS Program staff
- Alva Recinos (NINDS Analyst)
- Our contractor, Emmes and the CDE Team
- Our users



NINDS CDE Project



Created in 2009 with 8 disease areas



First NIH Institute developing CDEs



Trans NIH effort



Other Federal Agencies



Non-profit Organizations



Academic Institutions



National Organizations



■ Benefits of Using CDEs

- Open-access (**regardless of funding source**)
- Free to use (NIH and non-NIH funded projects/grants)
- Non-copyrighted instruments available
- Increase the precision (minimize variability)
- Improve efficiency (streamlined start-up. Don't reinvent the wheel!)
- CDEs can also be a tool to link datasets and examine relationships even if there is not a one-to-one mapping across all data elements in multiple datasets
- Faster data gathering—leading to powerful research to discover knowledge to improve healthcare and public health
- Lead to breakthrough science and data **FAIR**-ness (the process of making data more **F**indable, **A**ccessible, **I**nteroperable, and **R**eusable)

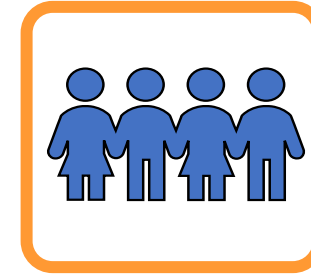
What is a CDE?



A precisely-defined question



Paired with a set of structured responses



Used in common across multiple sites, studies, datasets, research initiatives, etc.

variable_name	definition	permissible_values
RaceUSACat	The patient's self declared racial origination, independent of ethnic origination, using OMB approved categories	American Indian or Alaska Native; Asian; Black or African-American; Native Hawaiian or Other Pacific Islander; White; Unknown; Not Reported;



■ CDEs improve/promote:

- **Interoperability**—re-analysis, meta-analysis, and collaboration (across study designs, diseases/disorders)
- **Data Quality**—data aggregation across projects to increase statistical power and make data AI-ready
- **Reproducibility**—enhance scientific rigor, allowing comparison across studies and reducing inconsistencies
- **Efficiency of collection**—“off-the-shelf” data elements reduce time and costs to investigators
- **Efficiency of use**—facilitates data harmonization

...And add value to the
NIH Policy on Data Management and Sharing



■ How are CDEs
Developed?



CDE Development Process



CDES ARE IDENTIFIED, DEVELOPED, AND VETTED BY EXPERTS IN THE SCIENTIFIC COMMUNITY



COLLABORATIVE INVOLVEMENT WITH OTHER NIH INSTITUTES AND FEDERAL AGENCIES SUCH AS THE NATIONAL LIBRARY OF MEDICINE, CDC, DOD



ALIGNMENT WITH INTERNATIONAL DATA STANDARDS (ISO), CLINICAL DATA INTERCHANGE CONSORTIUM (CDISC), WHENEVER POSSIBLE



INSIGHT FROM PATIENT ADVOCACY GROUPS AND INDUSTRY



NINDS PROVIDES CONTINUOUS GUIDANCE, REVIEW, OVERSIGHT, AND UPDATES



■ Propose the development of new CDEs or revision of existing CDEs

- The [NINDS CDE Project Request Form](#) can be used to propose CDE development for Neurological disease/condition research areas with no existing CDEs, for development of a new subgroup of CDEs for an existing CDE set, or for substantial revisiting/revising an existing CDE set.



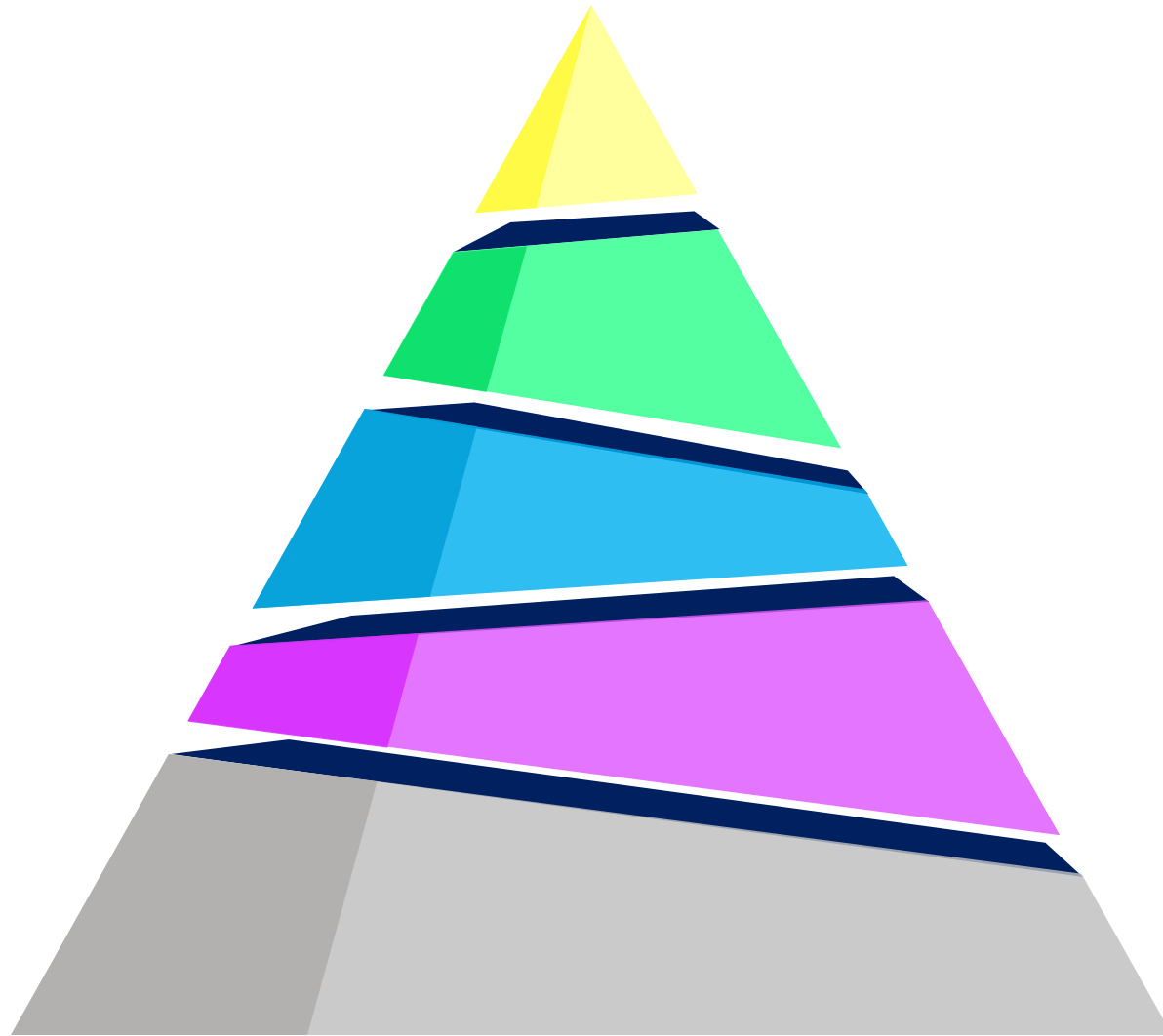
CDE Development Timeline



Total = ~ 18 Months



CDE Classification



- General Core
- Disease Core
- Basic*/Supplemental Highly-Recommended
- Supplemental
- Exploratory

*Classification term of “Basic” used for Traumatic Brain Injury CDEs.

Current NINDS CDEs by Disorder

General (For all diseases)

Amyotrophic Lateral Sclerosis

Cerebral Palsy ★

Chiari I Malformation

Epilepsy ★

Friedreich's ataxia

Headache

Huntington's Disease

Mitochondrial Disease ★

Multiple Sclerosis

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome

★ Includes pediatric-specific recommendations

NEUROMUSCULAR DISEASES ★

Congenital Muscular Dystrophy

Duchenne Muscular Dystrophy/Becker Muscular Dystrophy

Facioscapulohumeral Muscular Dystrophy

Myasthenia Gravis

Myotonic Dystrophy

Spinal Muscular Atrophy

NeuroRehab ★

Parkinson's Disease

Spinal Cord Injury ★

STROKE ★

Unruptured Cerebral Aneurysms and Subarachnoid Hemorrhage

TRAUMATIC BRAIN INJURY ★

Sport Related Concussion



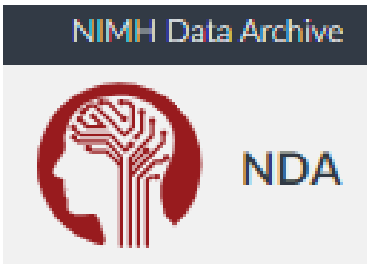
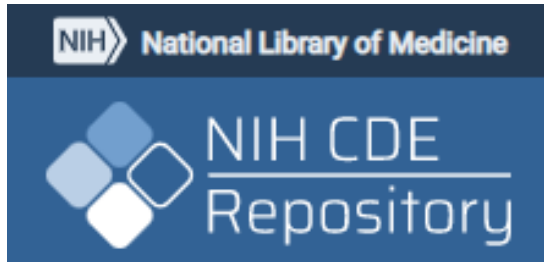
Parkinson's Disease
Version 2.0



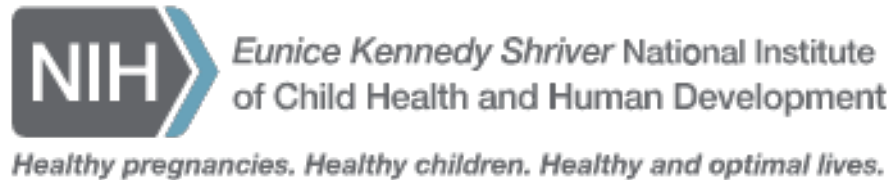
Mitochondrial Disease
Version 2.0



Pediatric CDEs at NIH



Built from BRICS



NINDS Common Data Elements

Harmonizing information. Streamlining research.

Streamline Your Neuroscience Clinical Research using content standards that enable clinical investigators to systematically collect, analyze, and share data across the research community.

The NINDS strongly encourages researchers who receive funding from the Institute to ensure their data collection is compatible with these common data elements (CDEs).



CDE Catalog

Users can search the Catalog to isolate a subset of the CDEs and to view and download details about the CDEs.



Library

The CRF Library contains the NINDS CRF Modules and various guideline documents that have been created through the NINDS CDE Project.

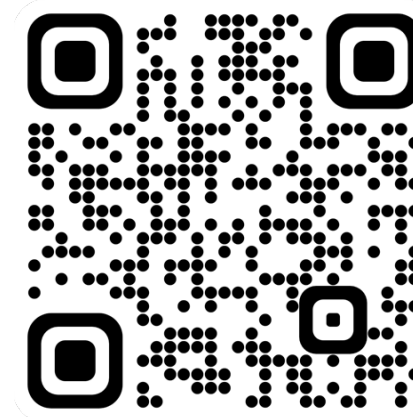


Form Builder

The Form Builder is intended to assist data managers and database developers to create data dictionaries for their study forms.

[Privacy Statement](#) | [HealthMeasures](#)

NINDS CDE Website



■ Things to Consider About CDE Use



- There is a learning curve for investigators and program staff
- Coordination is important to avoid duplication of effort
 - Different groups might develop slightly different CDEs to capture the same info
- Sometimes it is hard to retrofit (map) existing data to new CDEs
 - So, it is best to identify and use CDEs **from the start** of a research initiative

■ Implementing a CDE Initiative: a robust scenario

1) **Decide** that CDEs are desired for the research initiative

- Research funder (e.g., NIH)
- Regulatory agency (e.g., FDA)
- Professional society (e.g., American College of Cardiology)

2) **Choose** the CDEs to use

- Expert groups/stakeholders select from existing CDEs or develop anew
- Broader community engaged for input and buy-in
- Finalize CDE definitions

3) **Endorse & Require** CDE use

- Chosen CDEs are endorsed by the convening organization
- Use is mandatory (e.g., via terms & conditions of award)
- Compliance is monitored and enforced



Pandemic: Accelerated Use of CDEs at NIH

*The urgent need to **efficiently** collect **high-quality, interoperable data** is being addressed and coordinated across trans-NIH CDE efforts, including by:*

- COVID CDE Coordinating Committee
- RADx Executive Committee and RADx-UP Governance Committee CDEs
- Project 5 Common Data Model WG
- PhenX COVID Collection
- NIH PASC Task Force: Clinical Spectrum WG
- COVID-19 Pediatric CDE WG
- Maternal Health and Pregnancy in COVID
- NIH Public Health Emergency Disaster & Research Response
- RADx-RAD
- Serological Sciences Network
- BioData Catalyst
- NIH CDE Task Force
- **NINDS COVID-19 NeuroBiobank**
- NIH CDE Governance Committee

CDE Language - NINDS FOAs

- [PAR-22-142](#) Exploratory Clinical Trials (UG3/UH3 Clinical Trial Required)
- [PAR-21-237](#) Efficacy Clinical Trials (UG3/UH3 Clinical Trial Required)

UG3 Stage

1. Development of data management system, case report forms and data dictionaries, incorporating applicable NINDS **Common Data Elements** (CDEs) and other NIH-funded CDE Projects (e.g. [PhenX Toolkit](#));

NIH Resources: As appropriate, applicants are encouraged to make use of the following resources for clinical research including:

- PROMIS (<http://www.healthmeasures.net/explore-measurement-systems/promis>); and
- NINDS **Common Data Elements** (<https://www.commondataelements.ninds.nih.gov/#page=Default>).
- Clinical and Translational Science Award (CTSA) program (<https://ctsacentral.org/>);
- NeuroQOL (<http://www.healthmeasures.net/explore-measurement-systems/neuro-qol>);
- NIH Toolbox (<http://www.healthmeasures.net/explore-measurement-systems/nih-toolbox>);

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to address weaknesses in the rigor of prior research that serves as the key support for the proposed project approach, as appropriate for the work proposed? Are potential problems, alternative strategies for development, will the strategy establish feasibility and will particularly risky aspects be managed, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to include/exclude individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion/exclusion criteria based on the terms of the scientific goals and research strategy proposed?

Has appropriate consideration been given to utilizing the NINDS **Common Data Elements**?

NINDS Network Trials Using NINDS CDEs



Intramural Research



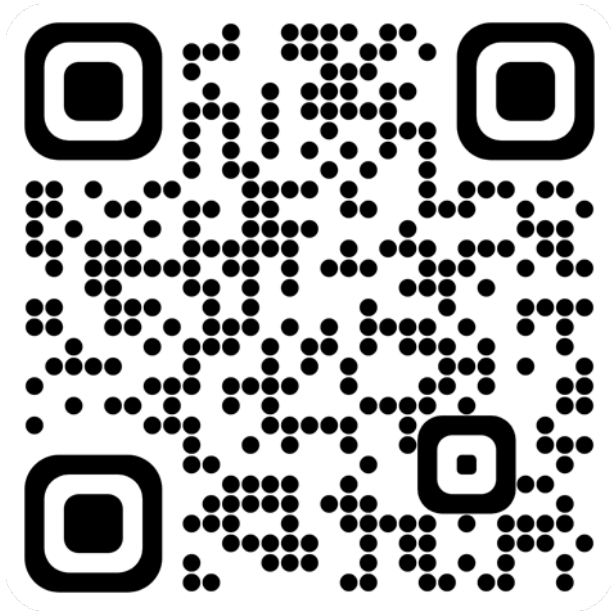


■ Limitations/ Challenges

- Many groups developing CDEs: Lack of consensus
- Copyrighted instruments may be expensive
- Variable validity in different populations
- May not be appropriate for non-clinical trials
- Pre-clinical CDEs are scarce
- Variability in interpretation and implementation



■ Accessing the NINDS CDEs



NINDS CDE Website

www.commondataelements.ninds.nih.gov

Contact NINDS CDE project team  **Emmes**

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Additional Resources

- **NIH CDE Repository** -- <https://cde.nlm.nih.gov/home> **Open Access regardless of funding source**
 - Tutorial for people new to CDEs: <https://www.nlm.nih.gov/oet/ed/cde/tutorial/index.html>
 - CDE Repository questions can be directed to nlm-support@nlm.nih.gov
 - Lots of general info and background in the NIH CDE Repository Resources page <https://cde.nlm.nih.gov/resources>
 - RADx-UP CDEs: <https://cde.nlm.nih.gov/cde/search?selectedOrg=RADx-UP>
 - NINR SDOH CDEs (gathered here in a single form): <https://cde.nlm.nih.gov/formView?tinyId=RJGlz6BY9>
 - Corwin EJ, Moore SM, Plotsky A, Heitkemper MM, Dorsey SG, Waldrop-Valverde D, Bailey DE Jr, Docherty SL, Whitney JD, Musil CM, Dougherty CM, McCloskey DJ, Austin JK, Grady PA. Feasibility of Combining Common Data Elements Across Studies to Test a Hypothesis. J Nurs Scholarsh. 2017 May;49(3):249-258. doi: 10.1111/jnu.12287. Epub 2017 Feb 23. PMID: 28231416; PMCID: PMC5426501. <https://pubmed.ncbi.nlm.nih.gov/28231416/>
 - Redeker NS, Anderson R, Bakken S, Corwin E, Docherty S, Dorsey SG, Heitkemper M, McCloskey DJ, Moore S, Pullen C, Rapkin B, Schiffman R, Waldrop-Valverde D, Grady P. Advancing Symptom Science Through Use of Common Data Elements. J Nurs Scholarsh. 2015 Sep;47(5):379-88. doi: 10.1111/jnu.12155. Epub 2015 Aug 6. PMID: 26250061; PMCID: PMC4618317. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4618317/>
- **NIH Data Management and Sharing Activities Related to Public Access and Open Science**
 - <https://osp.od.nih.gov/scientific-sharing/nih-data-management-and-sharing-activities-related-to-public-access-and-open-science/>
 - Includes links to the Final NIH Policy for Data Management and Sharing and Supplemental Information (October 2020) and guidance/resources about the policy
 - [NIH Plan to Increase Access to Scientific Data and Publication](#)
 - [NIH Strategic Plan for Data Science](#)
 - [NIH Public Access Policy](#)
- **CDEs and other Data Standards Resources from outside NIH that are relevant to research on health disparities**
 - HL7 Gravity Project (social determinants of health): <https://thegravityproject.net/>
 - PhenX (some content is in the NIH CDE-R, but not all)

NIH CDE Resources

CDE trainings

Standardize Your Research Data with the NIH Common Data Elements Repository

90-minute, on-demand recording of October 4, 2022, training.

https://www.nlm.nih.gov/oet/ed/cde/2022_10_cde-r_training.html

Common Data Elements: Standardizing Data Collection

One-hour, on-demand, self-paced tutorial – a more general introduction to CDEs.

<https://www.nlm.nih.gov/oet/ed/cde/tutorial/index.html>

NIH CDE Repository

<https://cde.nlm.nih.gov/>

Repository technical support?

NLM-support@nlm.nih.gov

An official website of the United States government [Here's how you know](#)

NIH National Library of Medicine

NIH CDE Repository

CDEs Forms My Boards About Help

Use Common Data Elements for More FAIR Research Data

Common data elements (CDEs) help researchers share and combine datasets, meet funding requirements, and save time.

Search NIH-Endorsed CDEs Search All CDEs Search Forms

Search by topic, keyword, or organization

NIH-endorsed CDEs have been reviewed and approved by an expert panel, and meet established criteria. They are designated with a gold ribbon.

Explore Learn Submit

The image features a soft, watercolor-style background in shades of teal and light blue. The colors are blended together, creating a textured, painterly effect. In the center of this background, the words "Thank You" are written in a black, elegant cursive script. The text is the focal point of the image, set against the lighter, more saturated teal area.

Thank You