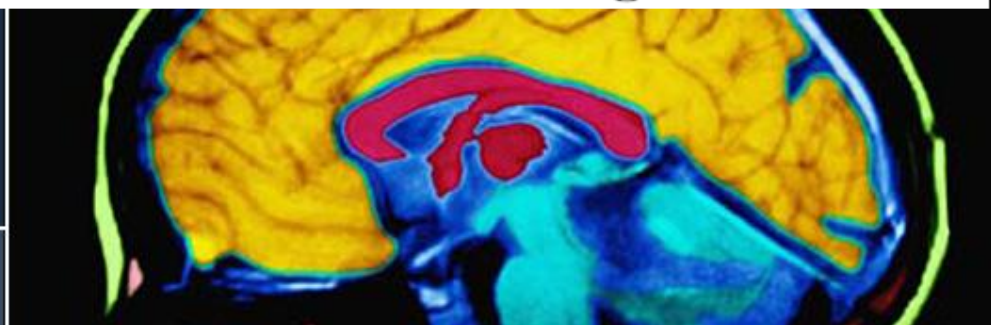
National Institute of Neurological Disorders and Stroke

NINDS Common Data Elements

Harmonizing information. Streamlining research.

Project Overview



Welcome to the NINDS CDE PROJECT

What is the CDE Project?

- NINDS initiated the development of Common Data Elements (CDEs) as part of a project to develop data standards for funded clinical research in neuroscience.

- The CDEs are content standards that can be applied to various data collection models and are intended to be **dynamic** and **may evolve** over time.

- CDEs are **not** a database.

What are the goals of the CDE Project?

- Develop **common definitions** and **standardize** case report forms (CRF) and other instruments

- Help investigators conduct clinical research through the development of these uniform formats by which clinical data can be **systematically collected, analyzed** and **shared** across the research community

What is a CDE?

- Standardized question and potential answers
- Allows for consistent collection and sharing of data
- Semantic value (the CDE name) with clear definitions and permissible values

Example:

- CDE name: "Birth head circumference value"
- Definition: "Circumferential measurement of the head at the …"
- Data Type: "Numeric Values"
- Input Restrictions: "Free-form Entry"

Case Report Form:

Prenatal and Perinatal History

[*Study Name/ID pre-filled*] Site Name: _____

Subject ID: _____

1) **Birth weight:** __ __ pounds and __ __ ounces OR __ __ __ __ grams

2) **Birth length:** _____ ☐ centimeters ☐ inches ☐ meters ☐ feet

3) **Birth head circumference:** _____ ☐ centimeters ☐ inches

4) **Gestational age value:** _____ weeks _____ days

CDE Details:

CDE ID	CDE Name	Variable Name	Definition / Description	Question Text	Data Type	Instructions	References	Population	Classification (e.g., Core)	Version #	Version Date	Aliases for Variable Name	CRF Module / Guideline	Sub-Domain	Domain	Previous Title	Input Restrictions
C12940	Birth head circumference value	BrthHeadCircumfVal	Circumferential measurement of the head at the widest point taken at birth - the distance from above the eyebrows and ears and around the back of the head	Birth head circumference	Numeric Values	Record the head circumference of the participant/subject in centimeters. If another unit of measure is preferred, it can be used, however the final data should be converted to centimeters. This is a pediatric-specific element.	Pryor H and Thelander H. (1968). Abnormally small head size and intellect in children J Pediatr. 73:593-598.	Pediatric	Supplemental	3.0	7/24/2013	Aliases for variable name not defined	Prenatal and Perinatal History	General Health History	Participant/Subject History and Family History	Birth head circumference value	Free-Form Entry

What are the objectives of the CDE Project?

- Identify CDEs used in clinical research
  - (age, gender, race, etc.)
- Present data elements in a standard format available to all
- Identify common definitions
  - (including permissible values, range checks, etc.)
- Standardize CRFs and other instruments
- Provide information to researchers for clinical data collection and sharing

Motivation & Overall impact of the NINDS CDE Project

Motivation

Trials were costing too much: no one believed in re-use of CRFs

Trials were taking too long and costing too much to get up and going

Data quality varied, no standards

Data collection was not consistent

Comparisons of data between studies was not possible

Impact

- Reduce time/cost to develop data collection tools
- Reduce study start-up time and cost of overall trial
- Improve data quality
- Facilitate collection of data
- Facilitate data sharing/comparisons between studies and meta-analyses

NINDS CDE Disease Areas – over 11,000 CDEs & 575 Instruments

General CDEs

Epilepsy*
Cerebral palsy *(new)*
Chiari I Malformation *(new)*
Headache
Mitochondrial disorders*
Movement disorders
- Parkinson's disease
- Huntington's disease

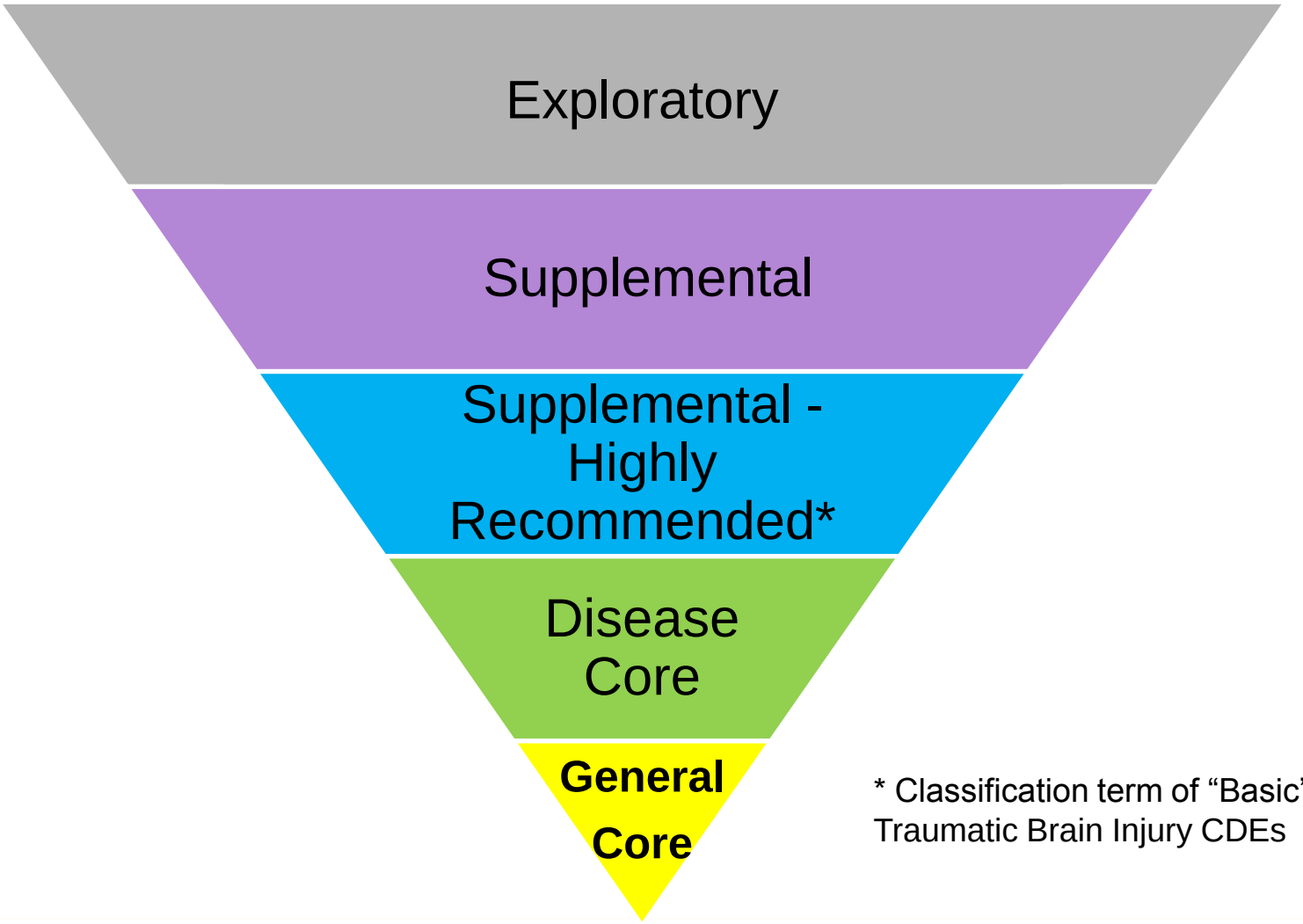
Multiple sclerosis
Spinal cord injury (SCI)*
Stroke*

Traumatic brain injury*
Neuromuscular disorders*
- Amyotrophic lateral sclerosis
- Friedreich's ataxia
- Muscular dystrophies
  - *Congenital, Duchenne/Becker, Facioscapulohumeral, Myotonic*
- Myasthenia gravis
- Spinal muscular atrophy

Subarachnoid hemorrhage (in development)
Sports-Related Concussion (in development)

** Pediatric Specific Recommendations*

CDE Terminology – Classifications



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

Core Classification

- **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.

Disease Supplemental - Highly Recommended Classification

- **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 Classification

- **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 Classification

- **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.

Developing New Recommendations for Clinical Research CDEs

- **Working Groups and NINDS CDE Team work together to develop disease specific research CDEs/CRFs:**
  - Collect and review data report forms from disease-specific and other outcomes databases
    - Registries, clinical research projects, etc.
  - Assess what can be shared between disorders from within the NINDS CDE website or other CDE-type activities
    - The greater the overlap and reuse of CDEs, the greater impact on future data-mining and data sharing
  - Identify appropriate outcome measures

CDE Development Process

- CDEs are identified, developed, and vetted by experts in the scientific community
  - **NINDS has hands-off approach**
- Process is transparent and inclusive
- NINDS provides continuous support and guidance
- Version 1.0 is not the end - CDEs are dynamic and will evolve over time

CDE Development Process, cont. (2)

Development Step	Typical Timeframe
NINDS invites Working Group (WG) members and WG Chair(s)	2-4 weeks
NINDS works with Chair(s) to divide WG into Subgroups and to nominate Subgroup Chairs	2-4 weeks
Introductory meeting of WG at national/international conference or via Web conference*	1-2 hours
Subgroups meet every 3-5 weeks via conference call to develop CDEs for assigned areas	6-9 months
Internal WG Review of all Subgroups' CDEs	1 month
Subgroups revise CDEs based on feedback from Internal WG Review	1-2 months
Public Review of WG's CDEs	6-8 weeks
Subgroups revise CDEs based on feedback from Public Review	1 month
Post Version 1.0 of CDEs on Web site	2-4 weeks
TOTAL	**12-18 months**

** If the WG does not meet in-person at the beginning of the process the NINDS schedules the in-person meeting to coincide with a large meeting/conference later in the process.*

CDE Development Process, cont. (3)

- Version 1.0 is not end – CDEs are dynamic and will evolve over time
- Process is iterative – plan to annually review and update CDEs
- Overall Steering Committee (SC), Data Management Committee (DMC) and disease-specific Oversight Committees (OC) formed to help maintain CDEs

Example of Disease-Specific Working Groups (WG)

- Biomarkers
- Demographics
- Cognitive/Behavioral/Psychological Outcomes
- Endocrinology/Diabetes/GI/Nutrition
- Exercise Physiology
- Genetics
- Imaging
- Neurological Assessments
- Patient Reported Outcome/QOL
- Vision
- Hospital/Care Management
- Pulmonary
- Cardiac
- Outcomes and Endpoints
- Therapies

Note: not all Disease- specific working groups have broken into sub-groups

Collaborative Effort: CDE Development & Implementation

- Expertise from close to 1000 specialists worldwide
  - Experts from every continent except Antarctica
- NIH institutes (17+), federal agencies (including FDA, CDC, VA, DOD, ACL, USUHS, AHQR, PCORI), and Nebraska State Health Department representative
- Collaborate with non-profits/foundations:
  - American Heart Association, American Academy of Neurology, Muscular Dystrophy Association, Prize4Life, ALS Association, Friedreich's Ataxia Research Alliance, CHDI Foundation, MA, United Mitochondrial Disease Foundation, Neurocritical Care Society, MRG, National Multiple Sclerosis Society, American Epilepsy Society, American Spinal Injury Association, ISCoS, Myasthenia Gravis Foundation of America, Sarah Jane Brain Foundation, Craig H Nelson Foundation, Parkinson's Disease Foundation, MJF, AACPDM, Chiari & Syringomyelia Foundation, etc…
- Pharmaceutical/Laboratories/ Companies
  - Allergan, Isis Pharmaceuticals, Cytokinetics, Glaxo Smith, Medtronic, BioMarin, Apotex Research, Merck, Stealth Peptides, Acorda Therapeutics, Edison, Novartis, Teva, EMD Serono, Biogen Idec, BrainScope, Bayer HealthCare, Sarepta Therapeutics, Banyan Group, MNG Labs, Coriell, etc…

Collaborative Effort: CDE Development & Implementation

- National Library of Medicine - NLM Repository Pilot Project and Assigning SNOMED, LOINC, RxNORM Values to NINDS CDEs
- NIH CIT BRICS – FITBIR and PDBP using the NINDS CDEs
- NIH-wide: PhenX, BRAIN, NIA's Alzheimer's Coord . Center, CaDSR, PROMIS, BMIC, etc…
- Harmonization with international data standards
- Clinical Data Interchange Standards Consortium (CDISC) & C-PATH
- NIH funded studies –part of our funding announcements
- Collaborate with non-profits/foundations to develop new CDEs and share CDEs for use in registries/studies
- Public (in the public comment period during development and feedback on our website)

CDE Products

- Web site contains:
  - ❑ CDEs
  - ❑ Data Dictionaries that define CDEs
  - ❑ Case Report Form (CRF) Modules
  - ❑ References to Instruments with ©
  - ❑ Procedural/Guideline Documents
- Web site also includes:
  - ❑ Summary of Updates
  - ❑ History and Acknowledgements
  - ❑ Feedback Form
  - ❑ References

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PROJECT OVERVIEW | CDE SEARCH | CRF SEARCH | FORM BUILDER | CONTACT

NINDS Common Data Elements

Harmonizing Information. Streamlining Research.

CDEs | Tools | Learn

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). Learn more about the CDE Project.

Launch Your Own Studies Faster

- Case report form modules
- Standardized data element definitions
- Instrument recommendations

Incorporate CDEs Into Systems

- Search for current CDEs
- Download CDE metadata
- Download Case Report Forms

Learn About the CDE Project

- Project overview and background
- Meetings and Presentations
- Collaboration with developers around the world

CDEs Now Available | CDEs Under Review | CDEs in Development

- General (CDEs that cross diseases)
- Amyotrophic Lateral Sclerosis
- Cerebral Palsy
- Chiari I Malformation
- Epilepsy
- Friedreich's Ataxia
- Headache
- Huntington's Disease
- Mitochondrial Disease
- Multiple Sclerosis

Privacy Statement | NeuroQOL | NIH Toolbox | PROMIS

NINDS Common Data Elements | NIH National Institute of Neurological Disorders and Stroke | NIH National Institutes of Health Turning Discovery Into Health

USA.gov

CRF Library

The CRF Library (a.k.a., Library of Case Report Form Modules and Guidelines) contains the NINDS CRF Modules (i.e., form templates) and various guideline documents that have been created through the NINDS CDE Project. Users are able to search the Library to find CRF Modules and Guidelines of interest.

Search Form

Disease: General (For all diseases)
Domain:
Sub-Domain:
© or TM:
Keyword:
Search Clear

125 items found. Download CRFs as a zip file
Items Displayed 50 Page: 1 of 3 First Previous

CDE Catalog

The CDE Catalog is a directory of the available NINDS CDEs. Users can search the Catalog to isolate (e.g., all stroke-specific CDEs, etc.), and to view and download details about the CDEs.

Search Form

Disease: General (For all diseases)
Domain:
Sub-Domain:
CRF Module:
Classification:
CDE Name:
Keywords:
From © or TM:
Population:
Search Clear

The table below only shows a portion of the CDE Catalog.
CDE Detailed Report shows more information about the CDEs.

Item count: 2065 (2030 distinct CDEs)
Items Displayed 50 Page: 1 of 42 First Previous Next Last

CRF Library for Form Builder

View Form Builder (0 Items)

The Form Builder tool allows users to assemble a case report form (CRF or "form"). Users create their form by customizing existing collections of CDEs (i.e., CRF Modules); they are able to delete CDEs from the existing templates and also able to add CDEs to the templates by choosing from the universe of all CDEs in the CDE Catalog tool. The Form Builder is intended to assist data managers and database developers to create data dictionaries for their study forms.

Search Form

Disease: General (For all diseases)
Domain:
Sub-Domain:
© or TM:
Keyword:
Search Clear

52 items found. Download CRFs as a zip file
Items Displayed 50 Page: 1 of 2 First Previous Next Last
Add items (selected items will be added to Form Builder)

Select All	CRF Module/Guideline	Description	© or TM	Download	CDEs	Version #	Version Date
☐	Demographics	This CRF Module contains data elements that are collected to describe the demographics of the study population. The items are used to compare baseline characteristics among study groups and to identify confounding variables.		CRF	CDE Details	4.1	06/29/2012
☐	Family History	The Family History at Baseline CRF		CRF	CDE	4.1	06/29/2012

PROJECT OVERVIEW CDE SEARCH CRF SEARCH FORM BUILDER CONTACT NATIONAL INSTITUTES OF HEALTH

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CDEs Tools Learn

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

CDEs Now Available | CDEs Under Review | CDEs in Development

Spinal Cord Injury (Coming 2014)
Mitochondrial Disease (Coming late 2014)

NINDS Vision for CDEs

- NINDS-funded trials use CDEs or are CDE-compatible – it is part of FOA and Terms of Award
- All types of clinical research can use part of the CDEs
  - Observational clinical studies can be linked to trial datasets
  - All human subject grantees are asked to consider using CDEs
- Clinical research progress will be accelerated
  - New investigators can build on consensus data elements
  - Start-up of multi-center and international clinical research efforts will be facilitated

Submitting Feedback on CDEs

- Feedback from users is key to ensuring project goals are met
- To submit feedback about data content:
  - Contact working group / organizers
- To submit feedback on variable names or proposed dataset structure
  - Submit feedback form on NINDS CDE website www.commondataelements.ninds.nih.gov

Accessing the NINDS CDEs

NINDS Common Data Elements Website

www.commondataelements.ninds.nih.gov

Submitting Feedback on CDEs

Feedback form on NINDS CDE website
http://www.commondataelements.ninds.nih.gov/ProjReview.aspx#tab=Feedback_and_Suggestions

For more information on the NINDS CDEs, please contact: NINDS CDE Project Officer, NINDS Office of Clinical Research at CRLiaison@ninds.nih.gov.