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 Form]

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:

<table>
<thead>
<tr>
<th>CDE ID</th>
<th>CDE Name</th>
<th>Variable Name</th>
<th>Definition / Description</th>
<th>Question Text</th>
<th>Data Type</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>C2940</td>
<td>Birth head circumference value</td>
<td>BirthHeadCircMul</td>
<td>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</td>
<td>Birth head circumference</td>
<td>Numeric Values</td>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Population</th>
<th>Classification (e.g., Core)</th>
<th>Version #</th>
<th>Version Date/Allele(s) for Variable Name</th>
<th>CRF Module / Guideline</th>
<th>Sub Domain</th>
<th>Domain</th>
<th>Previous Title</th>
<th>Input Restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatric</td>
<td>Supplemental</td>
<td>3.0</td>
<td>7/7/2013/Allele for variable name not defined</td>
<td>Prenatal and Perinatal History</td>
<td>General Health History</td>
<td>Participant/Subject History and Family History</td>
<td>Birth head circumference value</td>
<td>Free-Form Entry</td>
</tr>
</tbody>
</table>
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

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

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

* 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
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.
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 CR Liaison @ ninds.nih.gov.