What is the Common Data Element (CDE) Project?

• Meant to help investigators conduct clinical research through the development of uniform formats by which clinical data can be \textit{systematically collected, analyzed} and \textit{shared} across the research community.

• Central to the project is the identification of \textit{common definitions} and the \textit{standardization} of case report forms and other instruments.
Rationale for Project

• There are no widely used data standards in NINDS-funded clinical research

• Meta-analyses across studies often require extensive data re-formatting

• Multitude of data formats creates barriers to data sharing

• NIH Data Sharing Policy – CDEs provide the foundation
Specific Objectives

- Identify common data elements (CDEs) used in clinical research
- Develop common definitions for CDEs
- Standardize case report forms (CRFs) and other instruments
- Provide standard format by which clinical data can be systematically collected across research community

⇒ Will ultimately facilitate data sharing
Current Project Status

CDEs available for use are found at:

http://www.commondataelements.ninds.nih.gov/
Use of CDEs is not a requirement but...

NINDS is “strongly encouraging” investigators of Phase III and exploratory clinical trials “to use CDEs in their CRFs and data managements systems”

- PAR-11-173 (reissue of PAR-10-198)
- PAR-10-199
- Terms of Award for all Clinical Trials
What is a CDE?

- A logical unit of data, pertaining to information of one kind
- Has name, **precise definition**, and clear enumerated values *(if applicable)*
- Can be used in multiple **clinical studies**, as determined by a working group of experienced clinical researchers
What is a CDE? - Example 1

- Marital/Partner status

<table>
<thead>
<tr>
<th>CDE Name</th>
<th>Definition / Description</th>
<th>Code List / Permissible Values</th>
<th>Definitions for Codes / Permissible Values</th>
<th>Data Type</th>
<th>Guidelines/Instructions</th>
<th>Other Notes</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marital/Partner status</td>
<td>Current marital/partner status</td>
<td>Never married; Married; Domestic partnership; Divorced; Separated; Widowed;</td>
<td>Never Married — A person who has never been married or whose only marriages have been annulled. Married = A person currently joined in matrimony. Classify common law marriage as married. Includes married couples living together and not living together. Domestic partnership = A person who is a member of an unmarried couple, including same sex couples, living together in longstanding relationships, that are registered or unregistered.</td>
<td>Cher</td>
<td>Choose the current marital status of the participant/subject</td>
<td>No additional notes available</td>
<td>ceBIG CDE Public ID = 2188083</td>
</tr>
</tbody>
</table>
What is a CDE? - Example 2

- **Multiple sclerosis diagnosis type**

![Image](image_url)

<table>
<thead>
<tr>
<th>CDE Name</th>
<th>Definition / Description</th>
<th>Code List / Permissible Values</th>
<th>Definitions for Codes / Permissible Values</th>
<th>Data Type</th>
<th>Instructions</th>
<th>Other Notes</th>
<th>References</th>
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<tbody>
<tr>
<td>MS diagnosis type</td>
<td>The current MS diagnosis of the participant/subject</td>
<td>RIS; CIS; MS; NMO; ADEM; Other</td>
<td>RIS = Radiologically isolated syndrome; CIS = Clinically isolated syndrome; MS = Multiple sclerosis; NMO = Neuromyelitis optica spectrum disorder; ADEM = Acute Disseminated Encephalomyelitis; Other = Other CNS demyelinating disorder</td>
<td>Char</td>
<td>Choose only one. If &quot;MS&quot; is answered, go to question 2 to specify clinical course, then skip to question 6. If &quot;NMO&quot; is answered, go to question 3 to specify clinical course, then skip to question 7. If &quot;ADEM&quot; is answered, go to question 4 to specify clinical course, then skip to question 7.</td>
<td>No additional notes</td>
<td>No references available</td>
</tr>
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CDE Classifications:

1. **“General” Core CDEs**
   Relevant across neuroscience clinical research

2. **Disease-specific Core CDEs**
   Should be used in all studies for this disease

3. **Disease-specific Supplemental CDEs**
   Extended set that are “common”, but supplemental, i.e. not required - Choose from a “menu”

4. **Disease-specific Exploratory CDEs**
   Not yet validated, or under development

Coriell Forms or links to other repositories
CDE Development Overview

• CDEs are identified, developed, and vetted by experts in the scientific community

⇒ NINDS has hands-off approach, but provides guidance and support so that process is as transparent and inclusive as possible
### CDE Development Timeline

<table>
<thead>
<tr>
<th>Development Step</th>
<th>Typical Timeframe</th>
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<tbody>
<tr>
<td>NINDS CDE Team (NCT) nominates and invites working group (WG) members and working group Chair(s)</td>
<td>2-4 weeks</td>
</tr>
<tr>
<td>NCT 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 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>
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<tr>
<td><strong>Internal WG Review</strong> of all subgroups’ CDEs</td>
<td>1 month</td>
</tr>
<tr>
<td>Subgroups revise CDEs based on Internal WG Review feedback</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>
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Charge of CDE Working Groups

• **Develop** the CDE end products:
  ▪ Data dictionary of elements
  ▪ Template CRFs (not required but found to be useful by clinicians)
  ▪ Recommendation to use existing standardized instruments/scales – *Cognizant of copyright restrictions*
  ▪ Instructions/guidelines for use
  ▪ Summary of recommendations

• **Classify** CDE recommendations

• **Publish** CDE recommendations in journal
CDEs are not static

- Version 1.0 is not the end – CDEs are dynamic and will evolve over time
- Process is iterative – plan to annually review and update CDEs
  - CDE Oversight Committees help NINDS with this
CDE development is a collaborative effort

- **TBI** – Co-sponsored by NINDS, VA, NIDRR, DCoE, DVBIC
- **SCI** – Collaborated with Executive Committee of the International SCI Standards and Data Sets committees, ASIA, and other Spinal Cord groups
- **Stroke** – Incorporated data elements from AHA/ASA and CDC registries
- **PD** – Worked with CDISC to align the PD CDEs with existing SDTM standards to develop a PD-specific data standards specification and implementation guide
CDE Collaboration

• FITBIR database
• PD database
• MDA registry
• Canadian Institute for Health Information for their MS Registry
• Registering Various Core CDEs – Registered the CDEs in the NCI cancer Data Standards Registry and Repository (caDSR)
• Various Voluntaries requiring the use of the CDEs in grant applications
NINDS CDE Web site

www.commondataelements.ninds.nih.gov/
Google: “common data elements”

• Once finalized by the Working Group, CDEs are posted on the Web site for public access

• CDE Web site contains:
  ▪ CDE recommendations organized by disease
  ▪ CDE Catalog Tool – Search for CDEs
  ▪ CRF Library Tool – Search for template CRFs
  ▪ Form Builder Tool – Create customized data dictionaries
NINDS recently received assistance from NLM and CIT to improve CDEs

• CDE Team working with CIT and LHNCBC teams to:
  ▪ Eliminate redundancy in CDEs
  ▪ Resolve intra-disease and inter-disease inconsistencies
  ▪ Improve metadata of CDEs
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.
Learn Portal

- More information on:

  - CDE Development Process
  - Glossary of CDE terms
  - Tutorials – Coming Soon!
  - Obtaining Copyright Permissions
  - Clinical Studies using the CDEs
  - NIH/NINDS Data Sharing Guidance
  - How to Cite the CDE Project
NINDS CDE Team

Petra Kaufmann, MD, MSc – NINDS Director Office of Clinical Research

Joanne Odenkirchen, MPH – NINDS Project Officer, Office of Clinical Research

NINDS staff who have helped create CDEs: Robin Conwit, Rod Corriveau, Marian Emr, Brandy Fureman, Wendy Galpern, Amelie Gubitz, Katrina Gwinn, Ramona Hicks, Scott Janis, Naomi Kleitman, Elizabeth McNeil, John Porter, Linda Porter, Marg Sutherland, Ursula Utz, and Steven Warach

Contractors: KAI team, now Emmes team
NINDS Web site:
www.commondataelements.ninds.nih.gov

NINDS CDE Contact: Joanne Odenkirchen, MPH
jo21x@nih.gov