

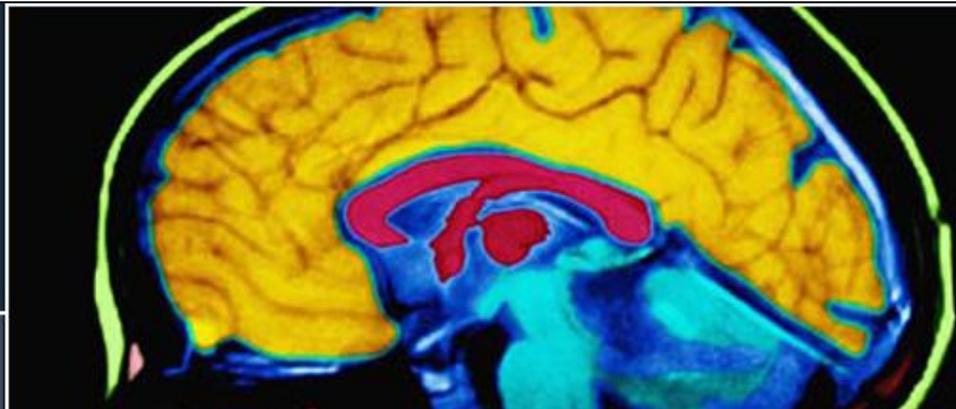


National Institute of
Neurological Disorders
and Stroke



NINDS Common Data Element (CDE) Project – Investigator Presentation Series

2016





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 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



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

General CDEs

Epilepsy*

Headache

Mitochondrial disorders*

Movement disorders

- Parkinson's disease
- Huntington's disease

Multiple sclerosis

Spinal cord injury (SCI)*

Stroke*

Traumatic brain injury*

* Pediatric Specific Recommendations

Neuromuscular disorders*

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

Cerebral palsy (in development)

Subarachnoid hemorrhage (in development)

Chiari & Syringomyelia (in development)



NINDS Vision for CDEs

- NINDS-funded trials use CDEs or be 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