Common Language for Clinical Research Studies: The National Institute of Neurological Disorders and Stroke/American Academy for Cerebral Palsy and Developmental Medicine Common Data Elements V1.0 Recommendations

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Objectives
The National Institute of Neurological Disorders and Stroke (NINDS) is the leading source of funding in the United States for clinical research for neurological conditions. To harmonize data collection, the NINDS Office of Clinical Research has led an effort to develop Common Data Elements (CDEs) for use in all clinical studies in neuroscience.

Through a partnership with the American Academy of Cerebral Palsy and Developmental Medicine (AACPD), the NINDS is promoting cerebral palsy (CP) specific CDEs as part of the NINDS project to develop data standards for all funded clinical research in neuroscience. The NINDS/AACPD CP CDE initiative strives to promote data collection in a consistent format, improve data quality, reduce study start-up time; and facilitate data sharing/meta-analyses.

Methods
1. AACPD CDE Working Groups (WG) consisting of worldwide experts is developing recommendations for all types of studies on CP. The composition of each WG includes clinical research experts within each of their domain areas. All recommendations are available for public review in Fall 2016.
2. The Steering Committee coordinated discussions with the goal of ensuring full representation of relevant CDEs across the continuum of CP research participant interactions and across the full range of WHO International Classification of Functioning, Disability and Health domains, assessments and outcome measures.
3. NINDS contractor organized and compiled the WG recommendations into CDE definition tables and case report forms.
4. Preliminary CDEs are posted for public review in 2016/2017.
5. Public comments are collated and incorporated into the final Cerebral Palsy CDE version 1.0 release.
6. NINDS staff remain largely hands-off through the development process, and more actively participate at the final stages to align the expert recommendations and classifications with those of other neurological disease CDEs.

Results
Cerebral Palsy Working Groups

- CDE Project Steering Committee
- Neurocognitive, Social, and Emotional Assessments
- Engagement and QOL Assessments/Data
- Health/Growth/Genetics/Labs
- Integrated WG Across Working Groups

Cerebral Palsy Start-Up Document

NINDS CDE Web site: www.commondataelements.ninds.nih.gov

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