Common Data Element (CDE) Domain Descriptions

Domain Name	Domain Description
Participant/Subject Characteristics	"Participant/Subject Characteristics" includes CDEs that characterize the study participant/subject, such as demographic information and socioeconomic status. CDEs included in this area are often used to meet reporting requirements characterizing study populations (i.e., NIH race and ethnicity elements), ensure balanced study design, and may be central to categorizing population differences.
Participant/Subject History and Family History	"Participant/Subject History and Family History" includes CDEs related to the participant's/subject's medical history and family history. CDEs in this domain query generally for conditions in the participant's/subject's history as well as for specific conditions related to the disease or disorder under study.
Disease/Injury Related Events	"Disease/Injury Related Events" includes recommendations for data elements that capture the course of the participant's/subject's disease or injury. This includes but is not limited to information related to the diagnosis, cause, symptoms, and complications.
Assessments and Examinations	"Assessments and Examinations" CDEs capture medical data on the participant/subject over the course of the study. This includes laboratory results, imaging data, physical/neurological examinations, vital signs, and other assessments and examinations of interest. Performance and outcome assessments are generally included in the domain "Outcomes and End Points" rather than here. **Note:** There is currently significant redundancy between the "Assessments and Examinations" and "Outcomes and End Points" sub-domains, particularly in the areas of cognitive and psychiatry measures. Once the CDEs are cleaned, "Assessments and Examinations" will include general CDEs created by NINDS Working Groups, and "Outcomes and End Points" will include measures of functional status (including cognitive, behavioral, psychiatry items).
Treatment/Intervention Data	"Treatment/Intervention Data" includes CDEs to capture the course of treatment, such as study drugs, surgeries and other procedures, and rehabilitation therapy. Data on treatments received as well as compliance to therapy may be collected.
Protocol Experience	"Protocol Experience" CDEs capture the participant's/subject's experience in the study. Informed consent, protocol compliance, and early termination are all areas that are characterized by the CDEs in this domain. These CDEs are not commonly used for data sharing purposes but are important for enrollment purposes and interpretation of results.
Safety Data	"Safety Data" CDEs capture medical events that occur to a participant/subject once enrolled in a study. These CDEs are important for consistently documenting these occurrences, regardless of relationship to the study intervention. The CDEs in this domain are especially important for clinical trials that intend to submit their data to a regulatory authority, such as the U.S. Food and Drug Administration (FDA).

Common Data Element (CDE) Domain Descriptions

Domain Name	Domain Description
Outcomes and End Points	"Outcomes and End Points" includes those outcomes and end points that are commonly used or highly recommended for the disease or disorder of interest. A large portion of the CDEs in this domain are CDEs from proprietary assessment measures, instruments, and scales, and may include the individual items captured from such measures as well as total scores. For more information on the use of assessment measures in the CDEs, see the CDE Web site page on "Obtaining Permission to Use Copyrighted Instruments/Scales": http://www.commondataelements.ninds.nih.gov/CopyrightPermissions.aspx