NINDS CDE Project Traumatic Brain Injury Version 3.0
Classification Definitions

General Core: A data element that collects essential information relevant and applicable to any study, regardless of the specific disease area or research domain. The NINDS and its appointed General CDE Steering Committee assign the General Core classification based on the current clinical research best practices. This classification applies to both the General CDEs and the Disease-specific CDEs. These CDEs are strongly recommended. General Core CDEs include information collected in all types of research, e.g., demographics and medical history. Link to CRF: General Core

Disease Core: A data element that collects essential information applicable to a disease-specific study. The NINDS and its appointed working groups assign CDEs/instruments to the disease "Core" Classification based on the current clinical research best practices. The disease Core CDEs are a small subset of CDEs, that are recommended to be collected by investigators. These are strongly recommended for all disease-specific studies.

For validated instruments: Strong evidence (SE) and applicable across all study designs (AD) and all TBI domains (AT) – SE-AD-AT

For CRF-CDEs: Applicable across all study designs (AD) and all TBI domains (AT) – AD-AT

Please note: CDEs or instruments that are applicable only to adult or pediatric populations can be classified as Core.

Supplemental – Highly Recommended (S-HR): A data element which is strongly recommended based on certain disease conditions or study types in clinical research studies. In most cases, these have been used and validated in the disease area.

For validated instruments: Strong evidence (SE) and applicable across all study designs (AD) but only some TBI domains (ST) – SE-AD-ST

For CRF-CDEs: Applicable across all study designs (AD) but only some TBI domains (ST) – AD-ST

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 should only be collected if the research team considers them appropriate for their study.

For validated instruments: Strong evidence (SE) and applicable across some study designs (SD) and some TBI domains (ST) – SE-SD-ST

For CRF-CDEs: Applicable across some study designs (SD) and some TBI domains (ST) – SD-ST

Classification	Level of Evidence*	Study Design	TBI Domain
Core	SE	AD	AT
Supplemental – Highly Recommended	SE	AD	ST
Supplemental	SE	SD	ST

SE = Strong evidence – An instrument must have strong evidence based on demonstrated reproducibility, i.e., at least two well-designed validation studies exceeding validation construct thresholds (see Christoforou et al., 2020). *Only applies to instruments NOT CRF-CDEs.

AD = Applicable across all study designs: Clinical Trials, Observational Studies, Comparative Effectiveness Studies, and Epidemiologic Studies.

SD = Applicable across some study designs (must apply to at least one of the following): Clinical Trials, Observational Studies, Comparative Effectiveness Studies, and Epidemiologic Studies.
SGs will determine if an instrument or CDE is appropriate for a particular study design, evidence of previous use is not required.

AT = All TBI domains – The Instrument or CRF-CDE is applicable for data collection across all TBI studies. For example, the GOSE (i.e., a Global Outcome; Outcomes and End Points instrument) or Injury date/time (i.e., a History of Disease/Injury Event; Disease/Injury Related Event CRF-CDE) would be classified as Core as each is applicable to studies focused on any domains/subdomains in TBI.

ST = Some TBI domains – The Instrument or CRF-CDE is applicable for data collection in some, but not all, TBI studies. An instrument or CRF-CDE does not need to be applicable to all subdomains within a domain. Examples include: imaging CDEs that would only be collected if a study includes imaging or an outcome measure that would only be used if a study includes a specific construct of interest.

Domain = A broad categorization assigned to a group of CDEs to show relatedness during data collection (e.g., Participant Characteristics, Assessments and Examinations, Outcomes and End Points).

Subdomain = A detailed categorization for a group of selected CDEs to show their relatedness (e.g., Laboratory Tests or Imaging Diagnostics are subcategories in the Domain Assessments and Examinations).

See Recommendations Summary Spreadsheet for the list of TBI v3.0 Domains and Subdomains.

REFERENCES

Christoforou AN, Armstrong MJ, Bergin MJG, Robbins A, Merillat SA, Erwin P, Getchius TSD, McCrea M, Markowitz AJ, Manley GT, Giacino JT. An evidence-based methodology for systematic evaluation of clinical outcome assessment measures for traumatic brain injury. PLoS One. 2020 Dec 14;15(12):e0242811.