Common Data Elements (CDE) Sub-Domain Descriptions
Traumatic Brain Injury (TBI) CDEs

Sub-Domain Name	Sub-Domain Description
Demographics	CDEs in the "Demographics" Sub-Domain describe the demographic characteristics of the participant/subject, including age, gender, race, and ethnicity.
Social Status	"Social Status" CDEs relate to the participant's/subject's socioeconomic status, and include such CDEs as level of education and yearly income. These CDEs are used to further characterize the study population beyond the traditional demographic variables.
General Health History	The "General Health History" Sub-Domain captures data on the participant's/subjects medical history and family medical history.
History of Disease/Injury Event	CDEs that capture the course of disease or events related to the injury under study are included in the Sub-Domain "History of Disease/Injury Event". These CDEs collect information about the disease or injury prior to study enrollment.
Classification	Useful CDEs for classifying the disease or injury can be found in the Sub-Domain "Classification".
Second Insults	The "Second Insults" Sub-Domain refers to complications that co-occur or are otherwise related to the condition under study.
Discharge Information	"Discharge Information" includes CDEs to capture the status of the participant/subject at the time of discharge from the hospital.
Physical/ Neurological Examination	CDEs in the Sub-Domain "Physical/Neurological Examination" capture information related to the physician's examination of the participant's/subject's general health, particularly as related to the disease/condition under study.
Vital Signs and Other Body Measures	The "Vital Signs and Other Body Measures" Sub-Domain includes CDEs to capture vitals, such as blood pressure and heart rate, and body measures including height and weight.

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Sub-Domain Name	Sub-Domain Description
Laboratory Tests and Biospecimens/Biomarkers	The results of "Laboratory Tests and Biospecimen/Biomarker" analyses are included in this Sub-Domain. It also includes guidelines and example protocols for collecting biospecimens/biomarkers.
Imaging Diagnostics	Imaging results such as from MRI and CT scans are included in the "Imaging Diagnostics" Sub-Domain.
Drugs	Medications that are administered as part of the study protocol as well as those non-study drugs taken by the participant/subject concomitantly are captured in the Sub-Domain "Drugs".
Surgeries and Other Procedures	The "Surgeries and Other Procedures" Sub-Domain includes data on medical procedures administered to treat the participant/subject.
Therapies	The Sub-Domain "Therapies" includes CDEs capturing data on study treatments that fall outside the Sub-Domains of "Drugs" and "Surgeries and Other Procedures". Importantly, this Sub-Domain includes CDEs related to rehabilitation therapy.
Participant/Subject Identification, Eligibility, and Enrollment	Data on "Participant/Subject Identification, Eligibility, and Enrollment", such as date of informed consent and randomization information, are included in this Sub-Domain
Protocol Deviations *Used by the General CDEs, not in the TBI CDEs*	The Sub-Domain "Protocol Deviations" includes CDEs related to any change, divergence, or departure from the study design or procedures of a research protocol that is under the investigator's control and that has not been approved by the IRB.
Off treatment/Off Study	The "Off treatment/Off Study Sub-Domain" captures data related to the participant's/subject's study disposition. It includes information on whether the participant/subject completed the study or withdrew early, as well as information on how long the participant/subject received the study intervention, where applicable.

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Sub-Domain Name	Sub-Domain Description
Study Management *Used by the General CDEs, not in the TBI CDEs*	Template administrative forms are included in the "Study Management" Sub-Domain. For example, this Sub-Domain includes a template Screening Log and a template Participant/Subject Contact Information Sheet. There are few CDEs associated with this Sub-Domain, as most of the data collected on the administrative forms are never entered in a study database or shared.
Adverse Events *Used by the General CDEs, not in the TBI CDEs*	The details about medical events that occur to a participant/subject once enrolled in a study are included in the "Adverse Events" Sub-Domain. The CDEs in this Sub-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).
End Points	The "End Points" Sub-Domain includes outcomes that are not separately captured in the validated outcome measures. These "End Points" are typically clinical events that may serve as outcomes in a research study, such as the details of a participant's/subject's death.