

Traumatic Brain Injury Endpoints Development

The Traumatic Brain Injury Endpoints Development (TED) Initiative is a 5-year, Department of Defense (DoD) funded project that is working toward the ultimate goal of developing better designed clinical trials, leading to more precise diagnosis, and effective treatments for traumatic brain injury (TBI). TED is comprised of leading academic clinician-scientists, along with innovative industry leaders in biotechnology and imaging technology, patient advocacy organizations, and philanthropists, working collaboratively with regulatory authorities, specifically the US Food and Drug Administration (FDA). The goals of the TED Initiative are to gain consensus and validation of TBI clinical outcome assessment measures and biomarkers for endorsement by global regulatory agencies for use in drug and device development processes. This manuscript summarizes the Initiative's Stage 1 progress over the first 18 months, including intensive engagement with a number of FDA divisions responsible for review and validation of biomarkers and clinical outcome assessments, progression into the prequalification phase of FDA's Medical Device Development Tool program for a candidate set of neuroimaging biomarkers, and receipt of FDA's Recognition of Research Importance Letter regarding TBI. Other signal achievements relate to the creation of the TED Metadataset, harmonizing study measures across eight major TBI studies, and the leadership role played by TED investigators in the conversion of the NINDS TBI Common Data Elements (CDEs) to Clinical Data Interchange Standards Consortium (CDISC) standards. This paper frames both the near-term expectations and the Initiative's long-term vision to accelerate approval of treatments for patients affected by TBI in urgent need of effective therapies ¹⁾.

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Manley GT M D Ph D, MacDonald CL, Markowitz A, Stephenson D, Robbins A, Gardner RC, Winkler EA, Bodien Y, Taylor S, Yue JK, Kannan L, Kumar A, McCrea M, Wang KK. The Traumatic Brain Injury Endpoints Development (TED) Initiative: Progress on a Public-Private Regulatory Collaboration to Accelerate Diagnosis and Treatment of Traumatic Brain Injury. J Neurotrauma. 2017 Mar 31. doi: 10.1089/neu.2016.4729. [Epub ahead of print] PubMed PMID: 28363253.

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