

## **Transforming Research and Clinical Knowledge in Traumatic Brain Injury (TRACK-TBI)**

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Effective treatment of traumatic brain injury (TBI) remains one of the greatest unmet needs in public health. Each year in the US, at least 1.7 million people suffer TBI; an estimated 3.2 to 5.3 million people live with the long-term physical, cognitive, and psychological health disabilities of TBI, with annual direct and indirect costs estimated at over \$60 billion. The unique public-private partnership of investigators, philanthropy, and industry leaders brought together in the multicenter Transforming Research and Clinical Knowledge in Traumatic Brain Injury (TRACK-TBI) proposal share a mission to accelerate clinical research in TBI. The goal is to create a large, high quality TBI database that integrates clinical, imaging, proteomic, genomic, and outcome biomarkers, and provides analytic tools and resources to establish more precise methods for TBI diagnosis and prognosis, improve outcome assessment, and compare the effectiveness and costs of tests, treatments, and services.

The investigators hypothesize that this approach will deliver better characterization and stratification of patients, allowing meaningful comparisons of treatments and outcomes and thereby improving the next generation of clinical trials. Specific Aim 1. To create a widely accessible, comprehensive TBI Information Commons that integrates clinical, imaging, proteomic, genomic, and outcome biomarkers from subjects across the age and injury spectra, and provides analytic tools and resources to support TBI research. Specific Aim 2. To validate imaging, proteomic, and genetic biomarkers that will improve classification of TBI, permit appropriate selection and stratification of patients for clinical trials, and contribute to the development of a new taxonomy for TBI. Specific Aim 3. To evaluate a flexible outcome assessment battery comprised of a broad range of TBI common data elements that enables assessment of multiple outcome domains across all phases of recovery and at all levels of TBI severity. Specific Aim 4. To determine which tests, treatments, and services are effective and appropriate for which TBI patients, and use this evidence to recommend practices that offer the best value. The project will directly impact public health by creating an open-access Information Commons populated with robust Common Data Elements that will make international research collaboration a reality. Detailed clinical data on 3,000 subjects (11 sites) across the injury spectrum, along with CT/MRI imaging, blood biospecimens, and detailed outcomes, will be collected and analyzed, permitting the identification/validation of biomarkers, and identification of structural abnormalities that may be predictive of outcomes, making strides toward a new taxonomy for TBI. The infrastructure of integrated databases and imaging and biosample repositories will create a high quality, legacy database for current and future generations of international researchers.