



# Traumatic Brain Injury

Emmes is known for excellence in clinical trial support, and that stems from our roots in statistical science and unwavering dedication to delivering superior research support as a CRO since 1977. Emmes currently supports over 100 clients, including government, academic, foundations, and pharmaceutical/biotech industry on projects across more than 30 fields of study including neuroscience, both domestically and internationally. Emmes recently acquired Orphan Reach as part of the Emmes family.

Driven with purpose to conduct clinical research impacting human health and public policy, our neuroscience team has contributed to the testing of innovative therapeutic solutions for decades

## Traumatic Brain Injury Experience:

Over a decade served as the Data Analysis and Management Center (DAMC)

Emmes served DAMC for a program of 3 US Department of Defense sponsored Phase II studies investigating the potential efficacy of hyperbaric oxygen for the treatment of post-concussive symptoms following mild traumatic brain injury.

Emmes provided full-scope support as the DAMC including protocol development; statistical design and analysis support; site management and monitoring; regulatory support; data management; pharmacovigilance, and electronic trial master file support.

### Highlights Include:

- **Extensive data management/warehousing effort:** Development of data capture system to collect clinical data including modules for enrollment and randomization, specimen tracking, and electronic patient-reported outcomes; custom configuration for collection/management of data from external sources to include actigraph, EEG, and Holter heart monitor; integration with Picture Archiving and Communication System to house/manage DICOM images from complex MRI/CT protocol.
- **Massive TLF generation effort for clinical study reports:** Clinical study report for Phase II clinical trial contained 2200+ tables, listings and figures; Final statistical report for prospective longitudinal cohort study contained 1700+ tables, listings, and figure.
- **Vendor management:** Execution of NDAs and data use agreements for over 2 dozen subject matter experts.
- **Manuscript/Presentation support:** Co-authored more than 25 peer-reviewed manuscripts and more than 30 conference presentations to disseminate study findings to the scientific community.

For additional information on our Neuroscience Therapeutic Research Unit and Traumatic Brain Injury Experience, please visit

[www.emmes.com/neuroscience](http://www.emmes.com/neuroscience)