# Informatics Best-practices to Facilitate Data Sharing Using the Federal Interagency TBI Research (FITBIR) Informatics System

Theriaque, D.W. [1], Wilson, K.A. [1], Matthews, D.A. [1], Siege, C. [2]
[1]RTI International, Biostatistics and Epidemiology Division, Research Triangle Park, NC, USA
[2]RTI International, Research and Computing Division, Research Triangle Park, NC, USA

**Background**

The Federal Interagency TBI Research (FITBIR) Informatics System, developed by the NIH and Department of Defense (DoD), provides a secure informatics platform and data repository for the aggregation and sharing of TBI research data. FITBIR's centralized, standards-based approach promotes scientific collaboration through the use of well-characterized data elements and form structures, enabling data from disparate research projects and institutions to be integrated in a rigorous manner.

Core FITBIR activities, conducted jointly with the FITBIR Operations Team (OT) , include mapping data to common or unique data elements (CDEs & UDEs), creating form structures, populating the resulting templates with research data, and validating data files for import into the FITBIR system. While the tools and processes that comprise the system are robust, informatics systems at individual institutions may not be optimally designed or developed to align with FITBIR system requirements. This abstract discusses our approach to FITBIR integration vis-à-vis the DoD-funded Chronic Effects of Neurotrauma Consortium (CENC) and provides best-practice recommendations for clinical research informatics.

**Methods**

Design and development of the case report forms (CRFs) and the data management system (DMS) for the CENC took place prior to starting any formal process with the FITBIR OT. Our *post hoc* approach involved following FITBIR's well-established workflow for integrating legacy data. As part of those efforts we compared the content of each CENC CRF with the data elements and form structures present in FITBIR, evaluating variable definitions, data types, labels, and permissible values. We also created new forms structures and UDEs for variables that were either not present in FITBIR or did not map well to those that did exist within the system.

**Results**

Our efforts resulted in the identification of 17 CENC CRFs (31% of the total) within the FITBIR system. 37 CRFs were not contained within FITBIR and had to be developed. A comparison of the data elements and form structures for the 17 CRFs in common revealed good concordance between CENC and FITBIR versions. The presentation of items within CRFs was most similar, with generally only minor changes in language observed. We observed that permissible values (values associated with a given item-response), are routinely stored in FITBIR as text-based labels (e.g., 'Yes' or 'No') rather than as numerical values (e.g., '1' or '2') which are commonly used within DMSs. For measures that are scored, however, numerical data are submitted to the FITBIR system.

**Conclusion**

*Post hoc* strategies to map and migrate legacy data into FITBIR can be successfully employed, however an after-the-fact approach may result in sub-optimal data mappings through simple misrepresentation of data elements that may already exist within FITBIR data standards. This may limit utility of the data

for future research. The more integrative approach of performing FITBIR data mapping during the CRF design stage should result in increased efficiency in CRF and DMS design and development. Finally, regardless of whether data mapping is conducted *a priori* and *post hoc*, additional programming efforts will be required to ensure accurate translation of data to meet FITBIR-specific formatting requirements.