

# Executive Summary

Stakeholders of the Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System held their third meeting on July 19, 2021, to achieve three primary goals:

- (1) update stakeholders on FITBIR's current state and capabilities,
- (2) understand stakeholders' experiences with and expectations of FITBIR, and
- (3) foster discussion on how best to leverage FITBIR to better understand TBI and reduce its burden on patients and their caregivers.

This meeting is available for viewing at NIH Videocast (<https://www.videocast.nih.gov/watch=42047>)

## **FITBIR's Current State and Capabilities**

The meeting highlighted FITBIR's strategies to meet Findable, Accessible, Interoperable, and Reusable (FAIR) principles, with a focus on its development and use of common data elements (CDEs). Consistent with NIH's encouragement of data sharing under FAIR principles, FITBIR intends to expand its services as a FAIR repository for TBI data. Patients emphasized the importance of *reusability* in particular, agreeing that maximal data reuse respects patients who contributed data. To increase reusability of data stored within FITBIR as well as the ability to harmonize across studies, FITBIR will concertedly encourage inclusion of metadata and more extensive use of CDEs. In addition, FITBIR continues to improve its security, trustworthiness, and technical capabilities. FITBIR has achieved Federal Internet Security Modernization Act (FISMA) Moderate compliance and is working towards FISMA High certification; it has also received the CoreTrustSeal, has begun storing backup data off-site, and encrypts all data that is submitted into the system. FITBIR is also working toward using the Cloud for workspace and storage capabilities.

Additional information on FITBIR's CoreTrustSeal certification is available here:

[FITBIR News | FITBIR \(nih.gov\)](#)

## **Stakeholder Recommendations for FITBIR Users**

Throughout the meeting, speakers provided suggestions to help data submitters more easily use the data repository and improve data quality and usability for data accessors. Overwhelmingly, data submitters were encouraged to contact FITBIR Operations early in study development. Representatives of the Operations team can facilitate the data submission process by providing documentation, feedback, and guidance on aligning data acquisition with FITBIR data dictionaries. Data submitters were also advised to conduct periodic data validation before submission, to allow for early correction of potential issues. All prior submitters emphasized that the submission process requires more time and money than anticipated, which future submitters should account for in their budgets—FITBIR provides a submissions cost calculator to facilitate that budgeting. For data access, meeting participants described a range of experiences in accessing and interpreting available data. An emerging theme was the benefit of discussing the data with the original study team and/or having access to additional background information to understand data context.

## **Stakeholder Recommendations for FITBIR**

As FITBIR has grown, it has encountered a variety of new data management challenges. For example, earlier iterations of FITBIR did not include older or iteratively expanded data that would require controlling case report form (CRF) versions or consideration of the lifespan of a dataset; speakers highlighted both requirements and discussed ways of encouraging data submitters to update and revise their datasets as needed. Currently, FITBIR relies upon CDEs to facilitate harmonization; however, CDEs may not be sufficient for all types of research—in particular, model cards may be more effective for standardizing metadata. Some research projects—particularly cutting-edge research—require use of Unique Data Elements (UDEs), which necessitate thorough documentation and accurate data dictionaries from data providers.

Additional information on FITBIR's data dictionary is located here: [Data Dictionary | FITBIR \(nih.gov\)](#)

In addition to highlighting these new challenges, participants suggested ways for FITBIR to continue improving its longstanding efforts. Data accessors suggested that FITBIR develop a strategy to highlight a study's available data (e.g., whether a variable was collected from all participants or which variables are publicly available) so that data accessors can more easily determine which datasets would support their projects. To encourage collaboration, meeting participants recommended that FITBIR develop a forum where researchers can pose questions or form teams to pursue common goals. Additional recommendations included releasing some study data (e.g., demographics) early and developing a system for users to rate data quality.

## **Leveraging FITBIR to Address TBI Health Disparities**

An important upcoming project for FITBIR centers on identifying and addressing health disparities in TBI, which may require CDE revision and consolidation. Some vulnerable and underserved populations (e.g., racial and ethnic minorities, individuals who are homeless, survivors of intimate partner violence, or those disadvantaged based on geography or socioeconomic status) experience high levels of TBI as well as reduced access to care; as a large TBI data repository, FITBIR can provide a platform to address these disparities. In addition to reducing the overall prevalence of TBI, FITBIR-supported research aims to specifically reduce TBI prevalence in populations of higher risk.

### **Action Items:**

- 1) Develop a forum (e.g., discussion board) where FITBIR users can pose questions to each other and FITBIR operations staff, with access to an archive of previous questions and discussions
- 2) Develop a system for publishing case report forms based on selection of data elements from the FITBIR Data Dictionary
- 3) Improve strategies to cross-map study variables and case report forms
- 4) Enhance data query tools to simplify the identification of shared data across studies on specific variables
- 5) Patient Focus - Participate in more rapid data sharing (e.g., a limited dataset that may assist in defining the prevalence of TBI)
- 6) Assess and develop common data elements related to the Social determinants of health

Additional information about FITBIR is located here: [Home | FITBIR \(nih.gov\)](#)