

LIMBIC-CENC DATA AND BIostatISTICS CORE

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BLUF

- **Main Aims**: Manage *data capture* and *securely store* PLS data; Complete QA/QC on all PLS data; *Disseminate* data to investigators and FITBIR and provide analytical support.
- **Current Status**: Established cohesive and multifaceted Core; Developed and refined procedures for data capture, QA/QC, storage and management, and dissemination; Providing IT expertise.
- **Clinical Deliverables**: Provide IT expertise in developing and disseminating KTC products.
- **1-year Goals**: Establish and refine data capture and management procedures; Develop and optimize IT systems; and Disseminate data to FITBIR and investigators.
- **End of Cyce Goal**: Submit all LIMBIC-CENC data to FITBIR



Division of Tasks and Roles

VCU Team

- Data capture from enrollment sites and Call Center
- Develop MOPs and SOPs for data collection
- Provide training on data collection and data entry
- QA for data completion and consistency
- Liaise with enrollment sites and provide enrollment sites Performance Metrics
- Development, implementation, and maintenance of information systems
- Track FITBIR GUID generation
- Coordinate data requests; secondary support for fulfilling data requests
- Maintain recruitment and retention data
- Support Neuroimaging and Biomarkers Cores' data collection and QA/QC

SLC Team

- FITBIR submissions
- QC reporting
- Develop, refine and maintain data dictionary
- Analytic data set development
- Biostatistics support
- Data analysis
- Support Neuroimaging Core data QA/QC

Activities Completed: FITBIR Submissions

- Completed March 2021 submission (2nd submission for LIMBIC-CENC)
 - 92 forms by March 31, 2021
 - Participants who graduated to follow-up from October 2019 thru September 2020
 - Baseline and follow-up visits and telephonic interview data
- SLC DBC team, in collaboration with VCU DBC team, has significantly improved and enhanced streamlined data processing for each FITBIR submission. During each interval, all data undergo quality assurance and control processes to assure that accurate, valid, and consistent data are submitted to FITBIR.
- There have been two changes in this period submission:
 - No total score will be submitted for any forms, whether they are captured in Medidata or derived/calculated.
 - The reliability and completion codes are being included to allow investigators to decide whether to include or exclude records where reliability and completion codes may not be valid

Activities Completed: Data Requests

- During Q2 2021
 - DBC has completed and distributed 2 data requests to either investigators or biostatistics group for statistical analysis.
 - 3 data additional requests are underway as DBC works with the investigators
- Currently, the biostatistics group is working on data analysis for 6 further requests
 - *Is physical exercise and activity related to cognition and well-being after mTBI? A LIMBIC-CENC Multicenter Study* (Walker, W.)
 - *Characterizing cognitive and functional profiles by dementia medical record code status within the CENC multicenter cohort* (Walker, W.)
 - *Sleep quality in TBI patients and its relationship to neurodegeneration and inflammation: a comparison with symptoms of PTSD and depression* (Werner, K.)
 - *Influence of prior mild TBI and PTSD on Cognition in the LIMBIC-CENC multicenter cohort* (3 unique analyses; O'Neil, M., Walker, W., Kean, J.)



Lessons Learned

- Tracking and monitoring
 - CENC QA/QC findings
 - Protocol drift
 - Dashboard
- FITBIR
 - Intermittent close out analyses
 - Submit reliability codes
 - Pseudo-GUID tracker
- Internal data sharing
 - (more) Decentralized data analysis
 - Data Cube
- Scheduled collaboration between Cores
 - Neuroimaging Core
 - Biomarkers Core
 - Knowledge Translation Core

The screenshot displays the 'Data Cube Summary Page' for the 'BRFSS (Behavioral Risk Factor...) dataset. The page includes a sidebar with a 'Fields list' containing categories like Age, Education, Race, and Military Status. The main content area features several data tables:

Age_categorical	Count
18-24	26
25-35	591
36-44	444
45-55	379
Over 55	123
Total	1,563

Sex	Count
Female	203
Male	1,360
Total	1,563

Ethnicity	Count
Refused	6
Not Hispanic or Latino	1,260
Hispanic or Latino	285
Don't know / Not sure	12
Total	1,563

Race	Count
American Indian or Alaska Native	11
Asian	25
Black or African American	305
Don't know / Not sure	8
Other	74
Pacific Islander	12
Refused	12
Total	1,563

StudyGroup	Count
Group 1A: Combat ONLY (negative for mTBI outside of combat deployment)	271
Group 1B: Combat PLUS (positive for mTBI outside of combat deployment)	596
Group 2A: POST Combat (positive for TBI after first combat deployment)	152
Group 2B: PRE Combat ONLY (negative for TBI after first combat deployment)	255
Group 3: Unexposed (completely negative mTBI history; no past TBI ever)	289
Total	1,563

MilitaryStatus	Count
empty	4
Current Service Member	291
Former Service Member	1,268
Total	1,563

Education	Count
Grades 9 through 11 (So...	4
Grade 12 or GED (High sc...	224
College 4 years or more (...)	686
College 1 year to 3 years (...)	649
Total	1,563

ServiceBranch	Count
empty	297
Air Force	133
Army	825
Coast Guard	1
Marines	192
Navy	115
Total	1,563

mTBIGroup	Count
Exposed mTBI Positive	1,274
Unexposed mTBI Negative	289
Total	1,563

Summary

- **Research Deliverables:** Developed and refined:
 - System for data capture, storage and QA/QC
 - IT Systems and infrastructure updates (i.e., Study Portal, Contact Information Management System, Publication Committee Request Form)
 - Data request process (internal investigators) to include Data Request Infrastructure and Data Dictionary with search functionality
 - Tracking progress in real time
 - Ongoing monitoring, with site trainings and ongoing workshops as needed
- Data sharing with external investigators and larger scientific community
 - FITBIR submissions
 - Collaborating with the Knowledge Translation Center to create LIMBIC-CENC publication database and prognostic tool
- **1-Year Goals:**
 - Data capture system refined to add new data collection tools to include REDCap survey for baseline visits
 - Finalize and deploy web-friendly data dictionary with global search functionality
 - Provide analytical support to ongoing analyses
 - Develop and deploy self-service for retrieving fulfilled data requests
- **End of Cycle Goals:**
 - Submit all LIMBIC-CENC data to FITBIR
 - Establish repository of all LIMBIC-CENC data for secondary analysis
 - Share lessons learned to for managing data capture and management for large multi-site military longitudinal study



Questions