

AWARD NUMBER: W81XWH-14-1-0299

TITLE: Conversion of Clinical Data from the NABISH I & II into FITBIR

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CONTRACTING ORGANIZATION: Virginia Commonwealth University
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14. ABSTRACT The Specific Aims of this project were to: 1) prepare the data sets from NABISH I, II and IIR for upload into FITBIR, 2) upload the data to FITBIR using their required validation and upload procedures, and 3) verify that these data were uploaded correctly. Substantial progress was made during the original award period (9/31/2014-9/29/2015). In September 2015, the PI, Dr. Miller accepted a new position and relocated to Virginia Commonwealth University (VCU). At this time original funding site, Baylor College of Medicine (BCM), shut down the award, and all work halted. Efforts to transfer the award were more complex and time-consuming than anticipated, with receipt of the award at VCU finally occurring July, 15, 2016. In late October, 2016, Dr. Miller, the PI went on medical leave, retuning in early December, 2016. Difficulties with identifying a data services provider have delayed work on this project further. The continued project hiatus from 9/30/2016-9/29/2017 is described in this report.					
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Introduction: This report describes a project to prepare a related group of legacy data sets from the National Acute Brain Injury Study: Hypothermia I, II, and IIR for addition to the Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System. The Specific Aims of this project were to: 1) prepare the data sets from NABISH I, II and IIR for upload into FITBIR, 2) upload the data to FITBIR using their required validation and upload procedures, and 3) verify that these data were uploaded correctly. This has been a primarily technical project to add value to FITBIR through the provision of detailed, carefully monitored, and similarly structured data sets that included 465 subjects with severe traumatic brain injury. In addition, the standard clinical management for all three trials was consistent in that it conformed to the Guidelines for Management of Severe Traumatic Brain Injury¹⁻³, making these data a robust and valuable addition.

Work began in October 2014 with a projected completion date of December 2015. Good progress was made in achieving Specific Aims 1 and 2 of the Statement of Work through the end of August of 2015, when Dr. Miller, the project PI left Baylor College of Medicine to take a new position at Virginia Commonwealth University. Despite persistent efforts on Dr. Miller's part to facilitate the transfer of the award, this did not occur until July 15, 2016. In the year since the award was transferred, progress on the Specific Aims has been handicapped by a variety of problems, the most limiting of which was the need to change data services providers.

Keywords and Acronyms:

Common Data Elements (CDEs)
 FITBIR – the Federal Interagency Traumatic Brain Injury Research Informatics System
 Form Structures
 Hypothermia
 NABISH – the National Acute Brain Injury Study: Hypothermia I, II, and II Revised (IIR)
 Traumatic Brain Injury (TBI)
 Unique Data Elements (UDEs)
 Variable
 Variable-mapping

Accomplishments: With the award finally transferred to VCU in September 2016, we were looking forward to getting this project back underway. However, in August 2016, the data services provider for the project, Ms. Sierra Fourwinds, Silverwind Research, Inc., notified Dr. Miller that due to the long hiatus, she were no longer available to support this project. Then, from mid-October through December, Dr. Miller was out on medical leave.

As shown in Table 1 below, this year has been spent in trying to identify a viable alternative provider since the project cannot go forward without data services support. Ms. Sierra Fourwinds, Silverwind, was also a Co-Investigator on this project with primary responsibility for direction and supervision of all technical aspects of the data preparation, UDE preparation, technical documentation of the project, and all activities related to the upload of NABISH data into FITBIR; furthermore, she has worked with all the investigators on previous projects, thus having the advantage of being familiar with investigators as well as the data needs of the project. Finding replacement services has not been possible at this time.

Table 1: Timeline of Project Activities

Date	Event
8/23/2016	Notified by Silverwind Research that they will no longer be able to provide data services for project due to long delay in getting project transferred from Baylor to VCU

Table 1: Timeline of Project Activities

Date	Event
8/31/2016	Submitted request to VCU Bioinformatics Core (BIC) of the VCU CCTR to provide data services support for project
9/8/2016	Preliminary meeting with BIC about data services, that provided overview of technical data work required for the project, to orient BIC staff to the project, and to set up procedures to transfer project and data files from Silverwind to VCU
9/12/2016	Confirmatory email that BIC will provide services needed for project
10/18/2016-12/1/2016	Dr. Miller out for neck surgery
11/22/2016	Mod p00003 received to Extend Without Funds through 12/29/2017
12/7/2016	Notified by BIC that due to their University project load, this project would have to wait until 2017
1/12/2017	Silverwind Research notified of plan to transition project to BIC here
1/26/2017	Initiation of technical discussion about file transfers and other procedures to send work completed by Silverwind to BIC
1/27/2017	Secure file storage area created on Neurosurgery T: drive to receive files from Silverwind; access to T: drive for BIC staff requested
2/9/2017	Requests for FITBIR accounts submitted for BIC staff (M. Tran, T. Aro)
2/24/2017	Budget request changing payment for data services recipient from Silverwind to BIC approved
3/2/2017	BIC unavailable until after 3/17 to assist with project
5/18/2017	Efforts to get files transferred from Silverwind to BIC put on hold due to BIC's unavailability
June, July 2017	Efforts to identify alternative resources at VCU or a commercial data services company in Richmond, VA that could support this project for available funds unsuccessful
7/28/2017	Notified A. Renner, Science Officer CDMRP, of problems with identifying data services provided for project and inability to move forward without these services

At the end of this Annual Reporting Period, we still were without a technical data service to complete this project. Dr. Miller has contacted Ms. Fourwinds at Silverwind Research in the hope that her schedule might have some availability at some point to assist with completing this project.

Since this project is not yet completed, we have no accomplishments to report regarding dissemination of the results.

Impact: The majority of work completed in the first eight months of this project were the clinical data mapping procedures to guide the technical data transfer and formatting procedures that would prepare the data for upload into FITBIR (Specific Aim 1). Without a data services provider to perform these next steps in the Statement of Work (Specific Aims 2 and 3), this project has been stalled for yet another year.

Changes/Problems: No changes to this project were made during this hiatus year of awaiting the transfer of the award.

Products: None at this point. Research projects conducted through FITBIR using the NABISH data, either as a focus or in combination with other data sets, will be future projects.

Participants & Other Collaborating Organization: The notable change in participating for this project has been the loss of Ms. Sierra Fourwinds, due to the long delay with the award transfer and the need for her company, Silverwind Research, to take on other business during that time. So, their services were not available when the award was finally transferred in the summer of 2016. Efforts to identify a new data services provider have not yet been successful.

Table 2: Project Personnel

Personnel	Role	Institution	Percent Effort
Emmy R. Miller, PhD, RN	Principal Investigator	Baylor College of Medicine (till 8/31/2015) Virginia Commonwealth University (current)	12
Sierra Fourwinds	Co-Investigator/Technical Director	Silverwind Research, Inc.	40
Stephen R. McCauley, PhD	Co-Investigator	Baylor College of Medicine	3
Elisabeth A. Wilde, PhD	Co-Investigator	Baylor College of Medicine	3

Special Reporting Requirement: None

Appendix 1: Reference List

1. Bullock R, Chesnut RM, Clifton G et al. Guidelines for the management of severe head injury. Brain Trauma Foundation. Eur J Emerg Med 1996;3(2):109-127.
2. Bullock R, Chesnut R, Clifton G et al. Part I: Guidelines for the management of severe traumatic brain injury. J Neurotrauma 2000;17.
3. Bullock MR, Povlishock JT. Guidelines for the management of severe traumatic brain injury. Editor's Commentary. J Neurotrauma 2007;24 Suppl 1:2.

Conversion of Clinical Data from the NABISH I & II into FITBIR

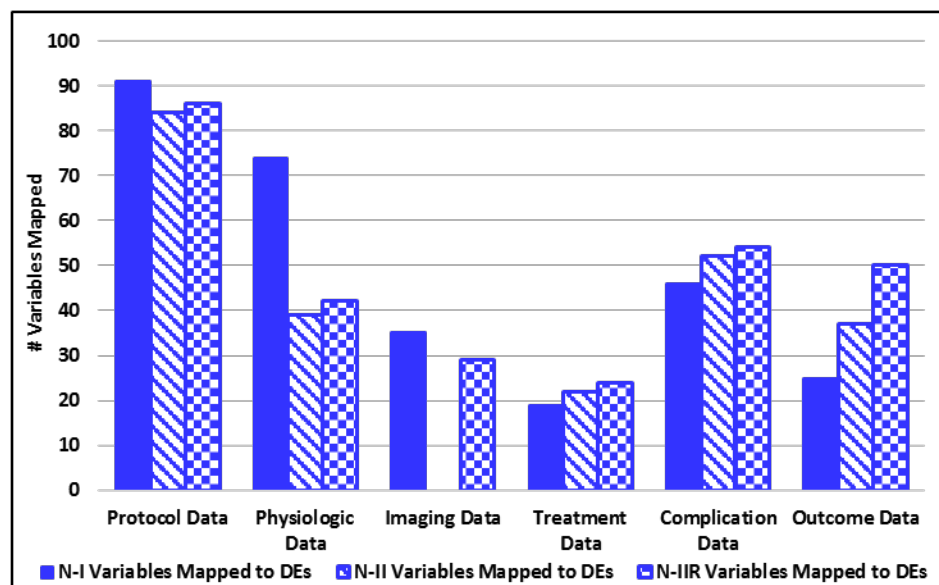
W81-14-1-0299

PI: Emmy R. Miller, PhD, RN

Org: Virginia Commonwealth University

Award Amount: \$115,263.00

- **Prepare data sets from NABISH I, II, and IIR for upload into FITBIR**
 - Review and analyze the NABISH data sets
 - Map NABISH variables to FITBIR CDEs where possible determine which remaining variables will be included as UDEs
 - Format variables, prepare required documentation and descriptions
 - Prepare subject identifiers needed for FITBIR to assign pseudo GUID for use during the upload process.
- **Upload data to FITBIR using their validation and upload procedures**
 - Prepare data submission request, establish account, and create study per FITBIR data submission policy and procedures
 - Prepare submission package(s) and submit to FITBIR; collaborate as needed to facilitate upload procedures.
- **Verify that data have uploaded correctly**
 - Submit test queries requesting data in all categories.
 - Compare data sets obtained through these test queries to original study data; resolve discrepancies



Timeline and Cost

Original Funding Period – Sept 30, 2014 – Sept 29, 2015
 Expected No-Cost Extension Year Funding – Sept 30, 2015 – Dec 29, 2018
 Key: **blue** – planned, **green** – actual, **gray** – project on Hiatus

Calendar Year	2014	2015				2016				2017				2018				
Activities	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Obtain approvals; administrative set up					Project on hiatus													
Project Start-up																		
Prepare NABISH Data Sets for upload into FITBIR																		
Upload data into FITBIR																		
Verify that data have been uploaded correctly																		
Project close out																		
Estimated Budget (\$K)	\$29	\$29	\$29	\$28		NCE	NCE	NCE	NCE	NCE	NCE	NCE	NCE	NCE	NCE	NCE	NCE	NCE

Goals/Milestones (original)

CY14 – 4th Quarter Milestones – Approvals/Project Start-up

- ✓ Approval Baylor IRB; HRPO designation as a technical project

CY15 – 1st Quarter Goals – Analysis/Preparation of Variables

- ✓ Review NABISH data sets; map variables to FITBIR CDEs/UDEs

CY15 – 2nd Quarter Goals – Data Preparation

- ✓ Continue mapping/formatting NABISH variables
- ✓ Prepare definitions/documentation of variables, tables

CY15 – 3rd Quarter Goals – Continue Data Preparation/Formatting

- ✓ Finalize mapping/formatting

CY15 – 4th Quarter Goals (No-cost Extension) – Upload data to FITBIR, Verify upload and close out project

NOTE: Project on hiatus 8/31/2015 – 12/31/2017

Goals/Milestones (revised)

CY18 – Goals – Identify and train data services provider, complete data mapping, create/upload form structures as required by FITBIR, complete project and close out

Budget Expenditure to date

Projected Expenditure: \$115,263.00

Actual Expenditure: \$76,842

Date: Oct 2017 – Annual Report