

AWARD NUMBER: W81XWH-14-1-0299

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

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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, returning in early December, 2016. Project-related efforts in 2017-2018 focused on finding a data services provider to complete the technical work of preparing mapped data files for submission to FITBIR. Inability to identify a data services provider has ultimately prevented the completion of this project.					
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Table of Contents

1. Introduction	1
2. Keywords	1
3. Accomplishments	1
4. Impact	2
5. Changes/Problems	3
6. Products	3
7. Participants & Other Collaborating Organizations	3
8. Special Reporting Requirements	3
9. Appendices	
a. Appendix 1 – References	4
b. Appendix 2 – Quad Chart	5

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) map study variables to FITBIR CDEs/UDEs to 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 period 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, as our original provider, Silverwind Research, Inc., became unavailable due to the long delay in transferring the award. Ultimately, it has not been possible to find a competent data services provider who could perform the remaining work for the amount of funding that remained, and procedures for early termination were followed.

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, 2017-2018 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
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, provided overview of technical 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 sometime later in 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 provider and inability to move forward without these services
11/3/2017	Updated A. Renner, Science Officer CDMRP, on status of finding a data services provider for the project
2/27/2018	Re-established contact with initial data services provider, Silverwind Research, Inc, initiated discussion about their resumption of data services work for this project, and resumed work on data-mapping, UDE definition, and other activities required to begin creating of FITBIR-ready data files
8/14/2018	Sierra Fourwinds, CEO of Silverwind Research, notified Dr. Miller that she was closing her company due to health reasons and so would be unable to assist with completing this project.
Late August, 2018	Contacted 2 local research data services companies informally about providing support for this project. Both unfamiliar with FITBIR and concerned about time required to learn ins-and-outs of system in order to support the project, as well as work required once that had been accomplished. Informal (over the phone/discussion) estimates ranged from \$80-100K to provide services, so did not request a formal bid as this was well beyond the resources of the project.
9/7/2018	Informed A. Renner, Science Officer CDMRP, that it was not possible to find a data services provider to complete this project. Procedures were then initiated for early termination of the project with refund of remaining funds.

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), it is impossible to complete the project.

Changes/Problems: Please refer to Table 1 and Impact discussion above.

Products: None at this point, as project cannot be completed.

Participants & Other Collaborating Organization: Please refer to Table 1 and Impact discussion above. Efforts to identify a new data services provider were not 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
<u>Sierra Fourwinds</u>	<u>Co-Investigator/Technical Director</u>	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.

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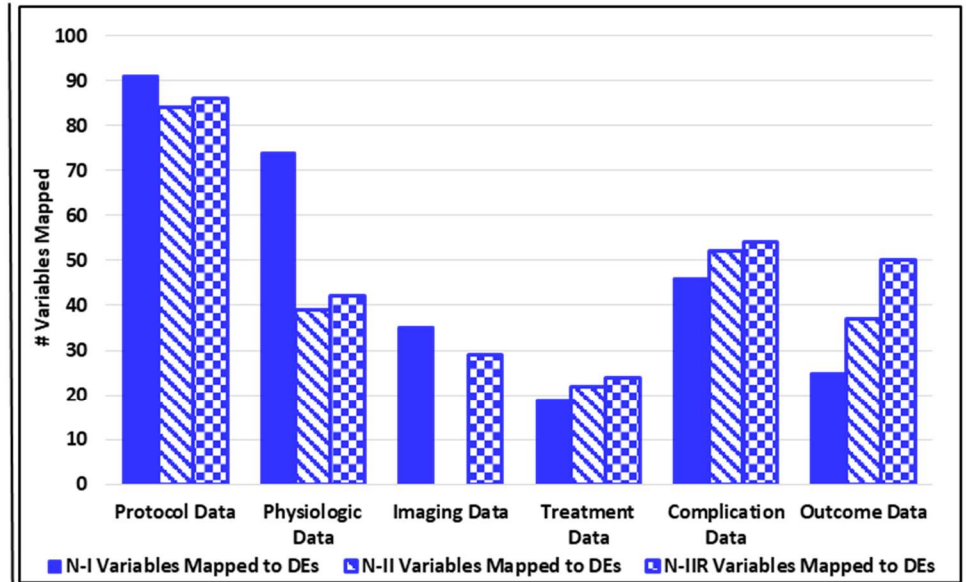
PI: Emmy R. Miller, PhD, RN

Org: Virginia Commonwealth University

Award Amount: \$115,263.00

Study Aims and Approach

- **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 31, 2017
 Key: **blue** – planned, **green** – actual, **gray** – project on Hiatus

Activities	2014				2015				2016				2017				2018			
	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Obtain approvals; administrative set-up	Blue	Green																		
Project start-up	Blue	Green																		
Prepare NABISH data sets or upload into FITBIR		Blue	Blue	Blue																
Upload data into FITBIR			Blue	Blue																
Verify that data have uploaded correctly				Blue																
Project close out				Blue																
Estimated Budget (\$K)	\$29	\$29	\$29	\$28	NCE	NCE	NCE	NCE	NCE	NCE	NCE	NCE	NCE	NCE	NCE	NCE	NCE	NCE	NCE	NCE

Project on Hiatus –
 - 2016 award transfer
 - 2017 no data services provider

No data services provider → early termination

Goals/Milestones (original)

- CY14 – Milestones** – Approvals/Project Start-up
- Approval Baylor IRB; HRPO designation as a technical project
- CY15 – Milestones** – Analysis/Preparation of Variables
- Review NABISH data sets; map variables to FITBIR CDEs/UDEs
 - Continue mapping/formatting NABISH variables
 - Prepare definitions/documentation of variables, tables
- CY16 – Milestones(No-cost Extension)**
- NOTE: Project on hiatus 8/31/2015 – 12/31/2017**
- CY17 – Milestones**
- Continue mapping/formatting NABISH variables
 - Identify alternative data services provider and begin file formatting
- CY18 – Goals** – Identify and train data services provider, complete data mapping, create/upload form structures as required by FITBIR, initiated complete project and close out
- CY 18 – STATUS** – Unable to identify data services provider; early termination procedures

Budget Expenditure to date
 Projected Expenditure: \$115,263.00

Actual Expenditure: \$88,836
Final Report - 2018