

**TRANSLATIONAL SCIENCE AT THE NEURAL INJURY CENTER**

MUS Research and Economic Development Initiative

Final Report

July 2017

*This document summarizes the accomplishments and impact for the whole project. For more details on specific individual objective tasks, please refer to the quarterly reports published on the MUS website for this award, <http://mus.edu/research/Funded/TraumaticBrainInjury.asp>*

### Accomplishments of the Project

**Objective 1: Expand current clinical capabilities of the Neural Injury Center (NIC) and support translational research.**

*The primary goal of this objective was to address the critical problem of traumatic brain injury (TBI) in Montana by evaluating, referring and aiding student Veterans with mild TBI (mTBI). An additional goal was to provide assistance with recruitment of subjects to support the aims of other MUS research initiative objectives of this project.*

The NIC met or exceeded all 5 milestones in the original proposal.

#### ***Major Objective Outcomes***

##### Serve and Screen Student Veterans and Improve Graduation Rates

- Of the ~500 veterans on the University of Montana campus at any given time, based on U.S. Department of Veterans Affairs statistics, ~15-20% may be suffering from a mTBI, either diagnosed or undiagnosed (75-100 individuals). Of those, 50-70% (45-70) may actively seek services at the NIC, as some are already receiving care in other places. Over the 2-year MREDI award period the NIC has been actively serving **42 student veterans**, primarily during the academic school year. An additional **15 student veterans** received assistance with needed medical referrals or campus resource provision through the NIC. Over half of those screened also received neuropsychological testing at no cost to them, as a result of financial support provided to the NIC via the MREDI grant.
- ~ 85% of the students seeking services were in their junior and senior years, or were in graduate school. Also, 75% of these students completed or are continuing their education at UM, despite the challenges of brain injuries.
- *A selection of comments by veteran patients about NIC services are included in the long-term impact section of this report.*

##### Other Community Members Served

- The NIC is a regular resource for screening of collegiate athletes at the request of UM athletic trainers and has accepted patients from Missoula, Montana and surrounding states for evaluation and screening. To date, **45** individuals were screened and assisted with referrals.
- Patient screening and follow-up visit rates have averaged 6-7 patients a month.

##### Serve as a Resource to Clinicians and the Broader Community

- The NIC hosted a large Continuing Medical Education (CME) conference to train over 100 regional clinicians in better diagnosing brain injuries and understanding the needs of TBI

sufferers. Nationally recognized speakers were invited to this conference, which furthered the goals of the collaborative research occurring at the NIC.

- Additionally, NIC clinicians and researchers have provided ongoing support to local and statewide clinicians as requested when referrals were made, to assist with interpretation of testing results.

#### Establish Medicare and Insurer Status for the Center to Allow for Broader Services

- Medicare approval was received in 2017 for the NIC clinic, which will operate under the umbrella of the existing UM Physical Therapy Clinic. The NIC has formed an active collaboration with the Clinic to continue to serve our students. Due to necessary funding-related restructuring, neurological exams will now be provided directly through the PT Clinic, as will oculomotor testing and balance testing. Many of these services will be billable and help to sustain them over time. Work is underway to identify a cohesive system for providing neuropsychology testing through the UM Clinical Psychology Clinic. We are optimistic all services will be available in full by Fall 2017. Ms. Laukes (Chief Operating Officer) will continue to be the entry point for all patients requesting NIC services and will conduct histories and serve as an ongoing support and resource.

#### Unforeseen Challenges

- Due to the unexpected retirement of the Director of the NIC and the inability to hire a neuropsychologist at 1.0 FTE on two-year contract into the NIC due to the current nationwide shortage of qualified neuropsychologist especially in the rural northwest, the Principle Investigators with the permission of MUS, re-budgeted funds allocated for these positions to the other project objectives to fund new milestones and commercialization ventures.

#### **Objective 2: Develop a comprehensive panel of objective tests to diagnose mild TBI (mTBI).**

*The overall goal of this objective was to develop and validate oculomotor, balance, cognitive, and blood-based microRNA diagnostic and prognostic tests.*

All milestones in the original proposal were met or exceeded.

#### ***Major Objective Outcomes***

- **170 subjects total**, TBI and non-injured controls have voluntarily participated in the development and validation of the oculomotor, balance, cognitive, and blood-based microRNA tests.
- The various testing modalities oculomotor, balance, cognitive and blood-based miRNA clearly identified **statistically significant differences** in measured parameters and demonstrated a high degree of sensitivity and specificity in distinguishing between control subjects and subjects with acute and chronic mTBI.

- The power of these individual diagnostic tests was enhanced when used in combination with each other i.e. oculomotor with balance or cognitive with miRNA and highlighted specific long-term neural impairments resulting from TBI in subjects.
- These findings and results have been published (3) or included in manuscripts being prepared (5) for submission to peer-reviewed scientific journals by project Principle Investigators.

*Degani AM, Santos M, Leonard CT, Rau T, Patel S, Mohapatra SM, Danna-dos-Santos A. The effects of mild traumatic brain injury on postural control. Brain Injury (2017) vol: 31 (1), pp: 49-56.*

*Mitra B, Rau TF, Surendran N, Brennan JH, Thaveenthiran P, Sorich E, Fitzgerald MC, Rosenfeld JV, Patel SA. Plasma micro-RNA biomarkers for diagnosis and prognosis after traumatic brain injury: A pilot study. J Clin Neurosci. (2017) Apr; 38:37-42. doi: 10.1016/j.jocn.2016.12.009. Epub 2017 Jan 20. PMID: 28117263*

*Rau TF, Patel SA, Guzik EE, Sorich E, Pearce AJ. Efficacy of a repeat testing protocol for cognitive fatigue assessment: A preliminary study in PCS participants. Concussion. (Accepted for publication June 19<sup>th</sup>, 2017).*

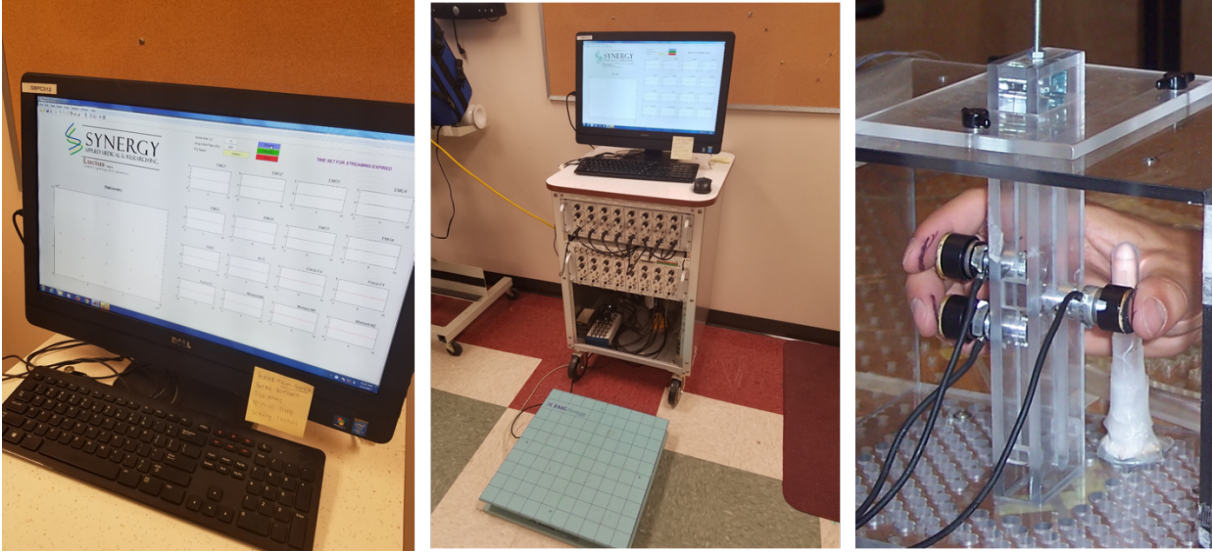
- We have found sensitive performance markers indicating the presence of long-term neural impairments. These diagnostic tests have been included in our daily operations of screening and referrals at the Neural Injury Center and are being moved to commercialization.
- New intellectual property (IP) developed or existing IP enhanced and patents filled with USPTO.
- Spinoff companies;
  - **Synergy Applied Medical and Research** created to commercialize two technologies, the balance assessment system (*BalanceLab*) and a system for acquisition and analysis of analog bio-signals (*Lucius vs 1.0*)-Drs. Santos & Mohapatra.

Subject undergoing assessment on BalanceLab during development





## Lucius System v1.0



Lucius interface and acquisition system of biological signals (Left panel). Application being used with balance and EMG equipment (Middle panel) and interface created for testing of multi-finger coordination and force production (Right panel). The system can also integrate any other instruments (thermocouples, encephalography, electrocardiography, etc.) and produce biofeedback to patients and researchers. Analytical system is customizable for future clinical use and systems are mobile.

- **FYR Diagnostics, LLC** created to commercialize blood-based miRNA for use as *in vitro* diagnostics-Drs. Patel & Rau.
- The Office of Technology Transfer at UM agreed a licensing agreement between Drs. Patel & Rau and Glia Diagnostics for the development of the miRNA TBI panel for a FDA approved *in vitro* diagnostic (IVD) test.
- Development of chemical switch technology for detection of miRNA in bio-fluid in a micro-fluidic testing platform progressing in collaboration with the Chemical & Biological Engineering Department at Montana State University. Validation of switch-like chemistry has yielded 15 new signaling outputs for miRNA-Dr. Stephanie McCalla.

### **Objective 3: Develop miRNA inhibitors to reduce neuropathology after TBI.**

*The goal of this objective was to develop and investigate a panel of novel miRNA inhibitors for potential intervention in TBI.*

Two of three milestones in the original proposal were completed. Two additional new milestones were added to the original proposal and completed.

## ***Major Objective Outcomes***

- 6 miRNA inhibitors of initially proposed 11 miRNA inhibitors were demonstrated to effectively antagonize target miRNA action *in vitro* in human and rodent cell culture based assays. A manuscript is currently in preparation for publication in a peer-reviewed journal.
- Rodent model of repetitive mTBI was successfully developed for testing and evaluation of miRNA based interventions. These finding and results have been published and shared with the TBI research community,

*Brooks DM, Patel SA, Wohlgelegen ED, Semmens EO, Pearce A, Sorich EA, Rau TF. Multiple mild traumatic brain injury in the rat produces persistent pathological alterations in the brain. Exp Neurol. 2017 Jul 27; 297:62-72. doi: 10.1016/j.expneurol.2017.07.015. [Epub ahead of print] PubMed PMID: 28756201.*

- Utilized our repetitive mTBI rodent model to evaluate and repurpose a previously FDA approved drug phenoxybenzamine (PZB) for neuroprotection following TBI. PZB delivered 8 hours after each injury produced a significant neuroprotective effect and reduced neurological impairment from repeated mTBI in the rodent model. A manuscript is being prepared for submission to a peer-review journal. This work significantly enhances the value of an existing patent owned by the University of Montana;

*Rau, Thomas Frederick (Stevensville, MT, US) Poulsen, David J. (Buffalo, NY, US), (2016) METHOD OF REDUCING NEURONAL CELL DEATH WITH HALOALKYLAMINES, United States THE UNIVERSITY OF MONTANA (Missoula, MT, US) 20160220515 <http://www.freepatentsonline.com/y2016/0220515.html>*

- Identified and curated a novel panel of ~30 miRNAs using next generation sequencing (NGS) for potential non-invasive blood-based diagnosis of chronic traumatic encephalopathy (CTE) from human brain tissue. Control and CTE brain tissue was obtained from the CTE Center VA-BU-CLF Brain Bank at Boston University in collaboration with Dr. Ann McKee. These findings have resulted in novel IP and subsequent preparation of a patent filing.

## **Objective 4: VAST: Next Generation Learning, Complete the development of a computer-based cognitive training (CCT) system for TBI subjects with cognitive impairment.**

*The primary goal of this objective was to utilize proprietary software algorithms to evaluate divergent thinking (DT) to develop and extensively test a mTBI cognitive training application for mobile devices.*

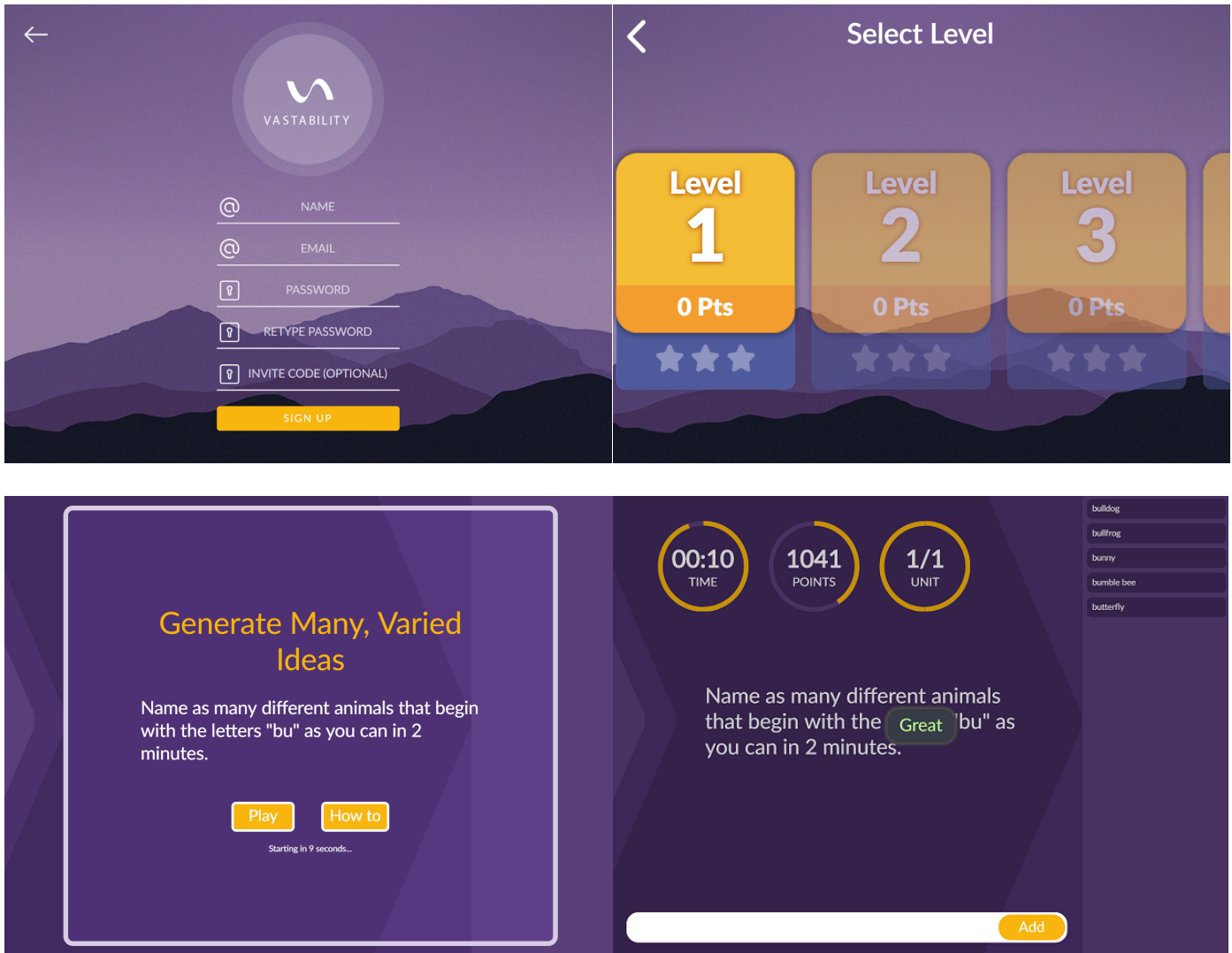
VAST exceeded the objectives of the original proposal and completed two additional milestones.

## ***Major Objective Outcomes***

- VAST completed the software development and deployment of the Divergent Thinking (DT) Training system (VastAbility) consisting of 10 levels of training for TBI subjects on iOS and Android mobile devices.

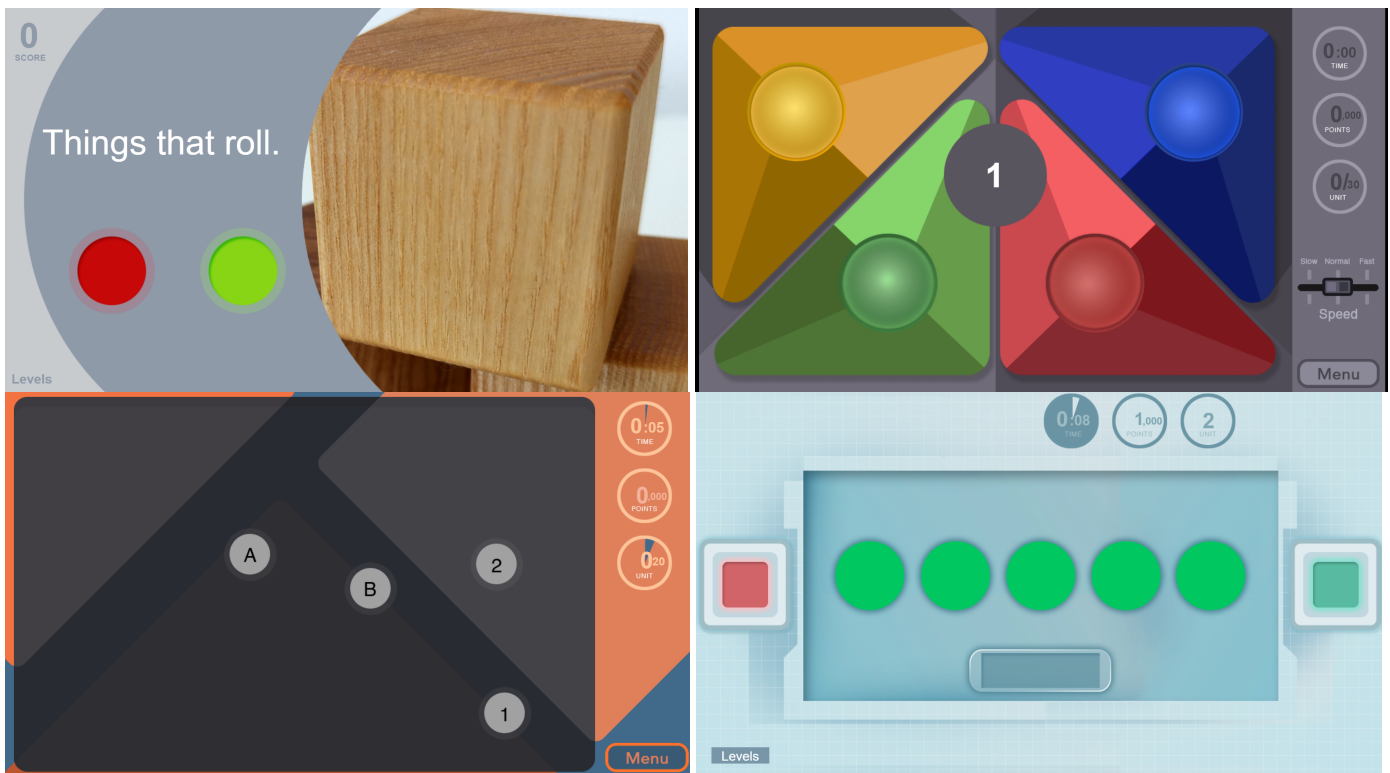
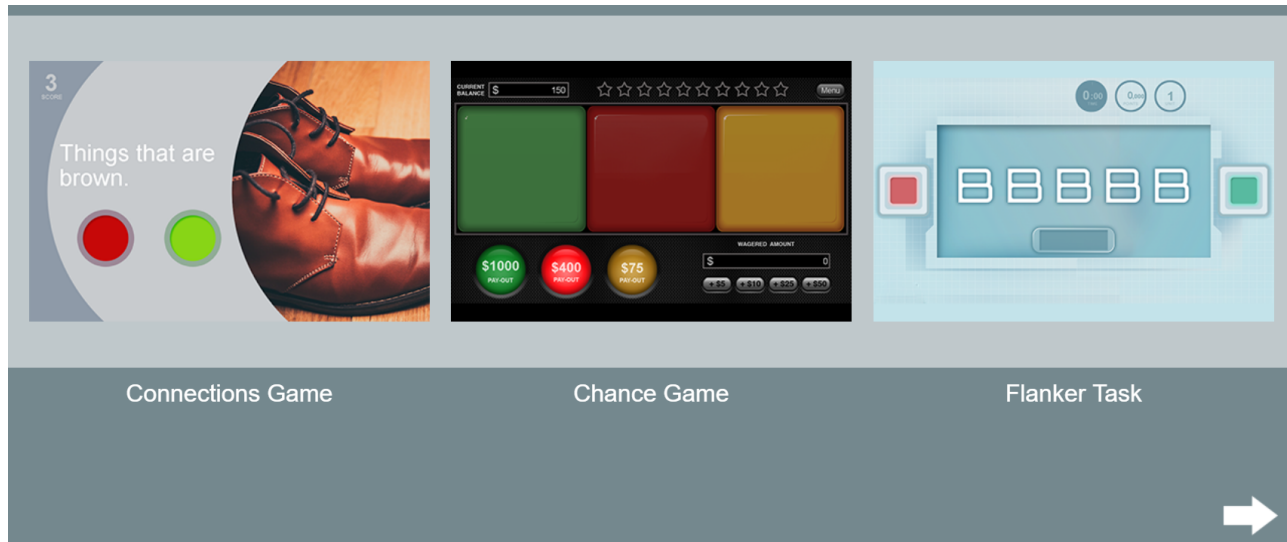
- VastAbility was pre-released on both the Apple App and Google Play store for further testing and development.
- Pre- and post-cognitive assessment data has been collected in control subjects with and without DT training application to determine effectiveness of the training platform.
- VAST is preparing for a controlled pilot clinical study using mTBI and non-TBI subjects.

Screenshots from VastAbility training system on iOS



- VAST also developed 8 additional mobile tests for improved diagnosis of frontal lobe injury among TBI subjects.
- Usability and feasibility training exercises tested in 500 adults, also tested in Tulsa, OK to determine usability as an intervention in age-related cognitive decline.

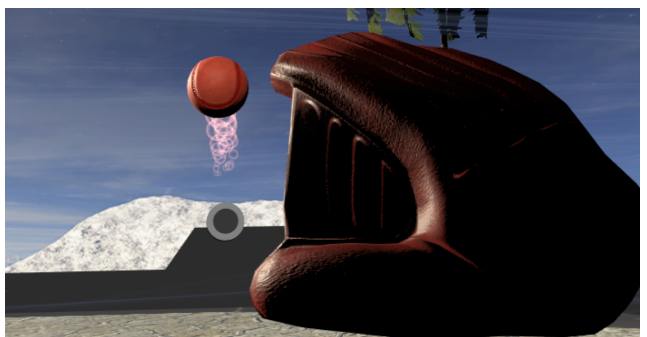
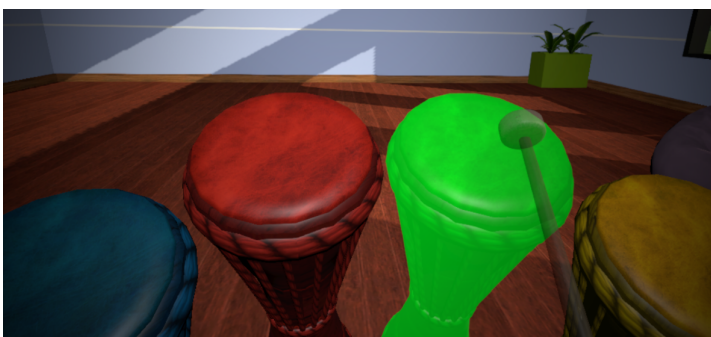
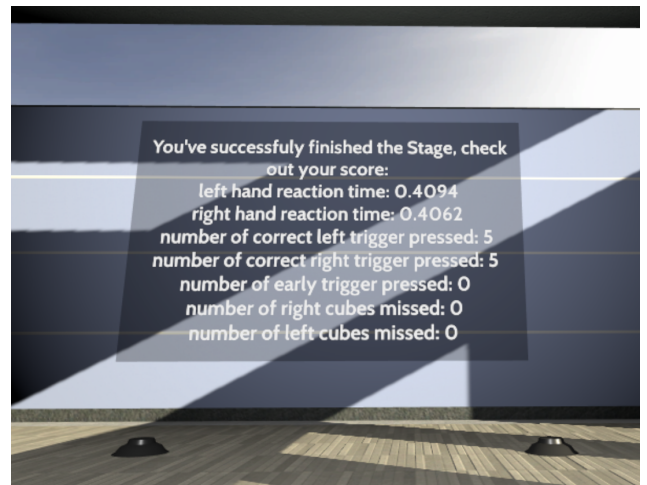
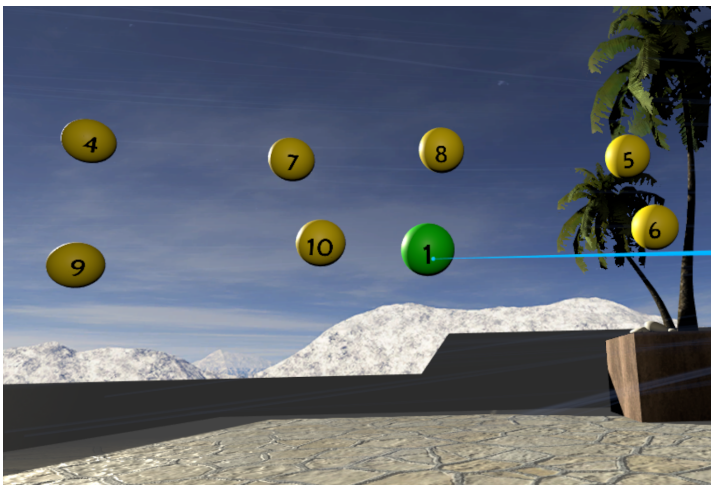
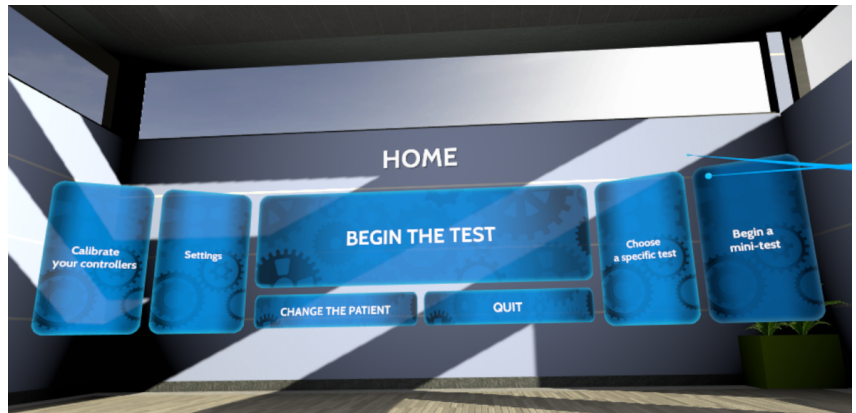
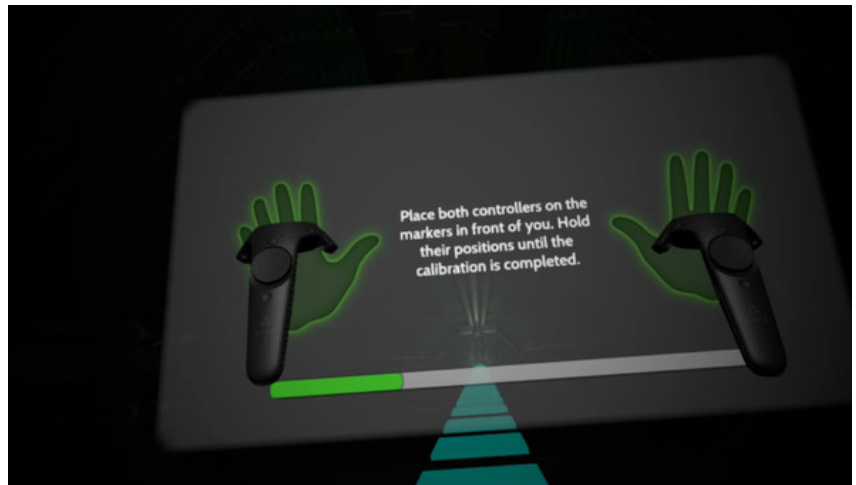
## Screenshots from CogFIT Frontal Lobe test system



- VAST for an additional milestone, developed a Virtual Reality (VR) diagnostic system for use among TBI subjects. VirtualMind is a virtual reality (VR) based neurocognitive test battery to aid in the assessment and management of traumatic brain injury (TBI)/concussion. VirtualMind assesses TBI subjects for a range of cognitive responses, including cognitive fatigue, subtle changes in physical coordination and reaction speed, cognitive processing speed, and the ability to concentrate on cognitive tasks. All cognitive tests are completed within an interactive VR environment that provides a more authentic and realistic testing solution compared to current cognitive testing.



VirtualMind system development and testing screenshots



**Objective 5: N-SITE, LLC: Complete the development and testing of a novel post-traumatic epilepsy (PTE) diagnostic analysis program.**

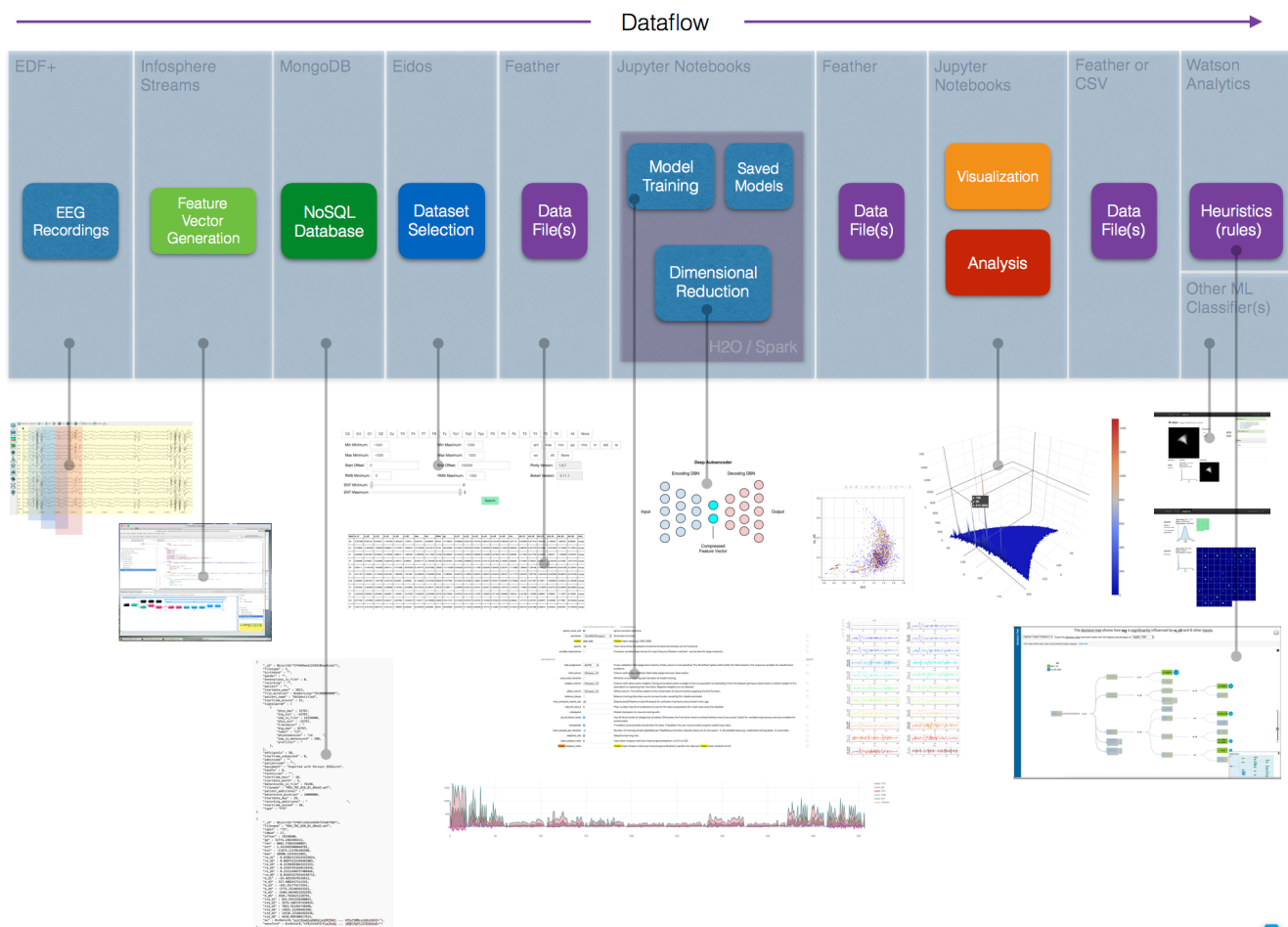
The goal of this objective was the evaluation and validation of a software system designed to help find particular patterns and signals in electroencephalogram (EEG) data predictive of TBI induced adult epilepsy.

N-SITE, LLC exceeded the objectives listed in Objective 5 of the original proposal.

**Major Objective Outcomes**

- Proprietary Eidos Discovery platform was completed and deployed for use at the University of Montana for analysis of archival EEG data from Massachusetts General Hospital, Boston, MA.

Novel EEG biomarker discovery work flow methodology for PTE developed by N-SITE, LLC



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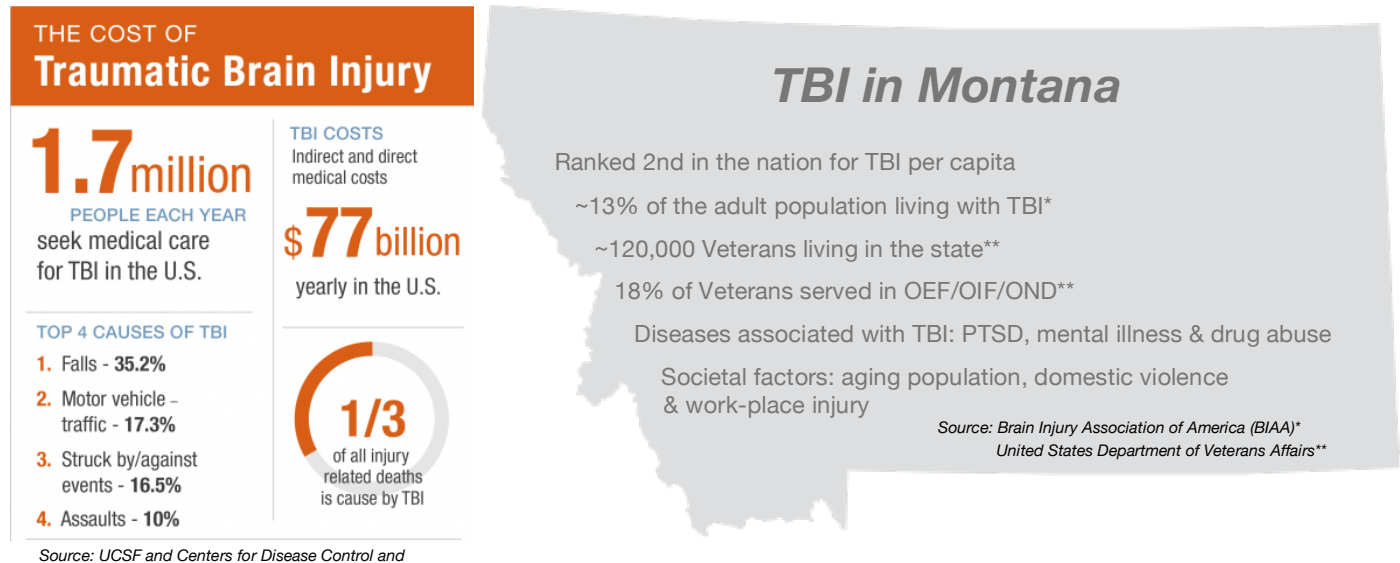


- Identified EEG biomarker signatures that distinguish and predict PTE based on EEG results.
- Establishing collaborations to deploying application in prospective large scale clinical trials for validation.
- New intellectual property (IP) developed or existing IP enhanced and patent filings being prepared for USPTO.

## Long-Term Impacts

### Neural Injury Center at UM

*Traumatic Brain Injury is a national public health issue and a silent epidemic in MT*



The MREDI award has supported the NIC to execute its core mission to address TBI in MT:

- To provide clinical services to students with a brain or spinal cord injury that may be interfering with their education and assimilation into the community.
- To conduct collaborative scientific research focused on traumatic brain injury (TBI) to transform laboratory discoveries into new therapies.
- To provide education related to neural injury for patients, families, clinicians, and the public. A special focus of the Center is on student veterans and their families.

To date the NIC has served or continues to support **102** individuals over the course of the MREDI award. Below is a selection of comments from some of these individuals regarding their experience at the NIC.

- "I'll be honest, after five and a half years of doctors, counseling and treatment, this was the best experience I've had regarding my injury. Finally found some people who seem to understand what a TBI does physically and mentally to a person. But perhaps more importantly understand that there is real hard science behind the condition instead of the "soft" science of "here's what historically we've been taught about TBI." I'm anxious to get some feedback from the group and I'll definitely avail myself of any opportunity to learn about treating and addressing my challenges. Thanks Cindi for your help, and please extend my gratitude to everyone on the team!"
- "I went to the Neural Injury Center not knowing what to expect...actually expecting a waste of time. Anything but! Cindi and the doctor were so kind and attentive! I genuinely felt "cared for" and not just another "experiment". They tested me and answered the questions I went in with. I plan on going back and following up with some more involved examinations. Thank you Cindi and to your team of professionals there at the Neural Injury Center! "

- “You have helped me in so many ways, that whatever you need to help with at the Center, I’m always here for you and ready to help!”
- “The Neural Injury Center gives me hope in helping me to figure out what if anything is wrong. That hope keeps me going. And without it, I would probably fail at what I am doing.”
- “I wanted to thank you for the meetings and for spending the time to listen. Thank you for putting me in touch with Dr. Harrison (the neuropsychologist). All the news I have gotten from the Neural Injury Center so far is good and it is really nice to have fewer worries as finals week approaches.”
- “I just wanted to thank you for taking the time to see me this afternoon. I tend to ramble on so your patience and understanding was really appreciated. I look forward to our next meeting and have a great weekend. Thanks again.”
- “I want to thank you very much for the help the Neural Injury Center has given me. I really appreciate the regular follow-up and communication. If there’s anything I can ever help you with, let me know.”
- “Thank you for your work. If it helps the progress of science and research I am quite willing to come back in if you need anything further. I really appreciate what you are doing.”

It has been central in establishing a model and structure that delivers critical clinical services, access to TBI resources and provides support to TBI sufferers and their families that are now offered to student veterans on campus, collegiate and local high school athletes and patients statewide.

The NIC has also placed considerable effort in understanding the barriers to the population of Montana receiving screening for TBI. This work has been spearheaded by Cindi Laukes. As a PCORI Scholar, she has completed a project entitled *“Encouraging Early Screening and Diagnosis of mild TBI in Two At-Risk Montana Populations: A Community-Based Approach to Identify Barriers and Culturally-Effective Interventions”*. This study is resulting in concussion education in those communities.

We are also exploring the possibility of establishing NIC clinics on campuses of other MUS institutions.

*The NIC will continue to serve as a unifying structure to assist with recruitment of research subjects, publicity, inform state and federal political delegations and military officials during visits and other coordinating functions.*

Public outreach efforts through seminars, meetings and presentations at conferences by NIC clinicians and researchers have disseminated information on TBI awareness and the capabilities of the NIC to the general public, health care providers and athletic trainers throughout Western Montana, in communities including Missoula, Helena, Great Falls and Butte. These events are continuing to expand the reach of the NIC statewide by fostering collaboration with physicians and physical therapy clinics.

Through the award the NIC has forged a pathway toward financial self-sustainability through billing insurance for services provided by clinicians and potentially for new testing developed by NIC researchers. This will be important to future expansion of the NIC model throughout the state of Montana.

In relation to this expansion, we are in discussions with the DC Veterans Affairs Office and VISN 19 about the possibility of creating a 5/8 VA position at UM about additional mechanisms for building VA

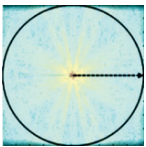


collaborations to better serve Montana Veterans at the VA Health Care VA system at Fort Harrison in Helena, outpatient clinics, community-based outpatient clinics and Vet centers throughout Montana.

A major milestone moving forward is the involvement of the NIC in coordinating multi-site clinical trials relating to TBI therapeutic interventions and diagnostics targeting veterans and TBI sufferers in the state of Montana. These opportunities will allow the patients of the NIC to be involved in these large-scale studies. The NIC is currently in negotiations with Tonix Pharmaceutical, New York, NY to finalize a contract to enroll subjects in a clinical drug trial for PTSD in collaboration with St. Patrick Hospital, Missoula, MT. Cindi Laukes will serve as primary study coordinator and primary PTSD Rater. The NIC & St. Patrick Hospital will receive \$9-10K per patient. The NIC is investigation further trials to host in Montana.

Finally, the success of the NIC over the duration of the MREDI award has resulted in the NIC receiving private donations with the goal of funding the construction a new building to centrally house the services provided by NIC with dedicated clinical and research space and facilities to better serve the campus, local and state communities living with the life-long effects of neural injuries.

- Spin-off company formed,
  - C.A. Laukes, LLC is a Montana-based clinical and health research consulting and services company, created to provide professional expertise and hands-on support to health, biotech, and medical research companies, health professionals, and research investigators. The owner has 24 years of clinical/health research experience working in multiple specialties, inclusive of neuroscience, neurology, neurosurgery, psychiatry, cardiology, oncology, internal medicine, women’s health, wellness, herbal medicine, and patient centered outcomes. Services include: Program/Project Management; Grant Writing and Management; Clinical Research Start-up, Training, and Program Restructuring; Research Network/Business Expansion; Medical/Health Writing, Editing, Publication Preparation; Investigator-Initiated Protocol Design, IRB Submissions; and Marketing Strategies.



## Objectives 2-5

Objectives 2-5 have resulted in the creation of new intellectual property for MUS, multiple spinoff companies, creation of new private sector jobs and grown emerging research sectors such as biomechanical engineering, molecular diagnostics, and virtual reality technologies.

## Objective 2

- Two extra-mural grant applications were funded through the Clinical Translational Research Infrastructure Network (CTR-IN).
  - “The Development of a Multi-Dimensional System of Oculomotor Evaluation for mild traumatic brain injury (mTBI)” July 2015-June 2016; PIs Dr. Santos & Dr. Rau **\$65,000** total costs.
  - "Rapid Screening of TBI in Student Athletes and Veterans of Rural Mountain West". July 2017-June 2018; Dr. Santos & Dr. Mohapatra **\$66,000** total costs

- Four other extra-mural funding initiatives are in multiple stages of development (**\$1.45 million requested**) including multi-site initiatives and collaboration with Montana State University, University of Nevada at Las Vegas, and the Veteran's Hospital at Puget Sound.
- **Glia Diagnostics:** Drs. Rau & Patel have facilitated a licensing agreement with Glia Diagnostics, an Australian biotechnology company. This agreement transfers intellectual property developed at the University of Montana under the MREDI program for TBI diagnosis using micro RNA biomarkers. UM will retain all ownership, and will receive royalty monies from this agreement.
- **Patent:** Patel SA and Rau T. "Detection of Traumatic Brain Injury" issued on March 28, 2017, as U.S. Serial No. 9,605,315.
- **Patent:** Patel SA and Rau T. PCT application entitled "Methods for the Detection of Brain Injury" UM Ref. Not Assigned. (14/669454) Date filed September 22, 2015



*Synergy Applied Medical and Research (Synergy Inc.)*

- Created by Dr. Santos for the commercialization of BalanceLab and Lucius technologies. In order to increase the likelihood of the company's success, Synergy Inc. formed a partnership with a Brazilian company (EMG systems of Brazil). This partnership was officially launched in January 1<sup>st</sup> 2017 when the commercial website was aired (<http://www.samrsolutions.com/>). Due to its growth, *Synergy* has one position opened for a sales representative.
- Synergy Inc. will conduct the development of instrumented technologies and implement clinical trials here in the State of Montana. This technology company is now on the track to attract capital and revenue to the Missoula area.
- A prototype of interface to allow mapping of TBI occurrences has been developed. This interface has been presented to members of the Traumatic Brain Advisory Council. The system would facilitate the process of recognize vulnerable areas, incidence, and quality of care. The first prototype was developed in Matlab language and currently awaits translation to Android/IOS platforms.
- Two students were trained under this award (one PhD and one MSc). In addition, a post-doctoral fellow was supported for 12 months through this same award. These professionals are now partners and employees of Synergy Inc.



- Co-founded by Drs. Patel & Rau, FYR Diagnostics, LLC in Missoula, MT. It is a preclinical and clinical biomarker development company identifying and validating microRNA biomarkers for traumatic brain injury and neurodegenerative disorders. From its founding, FYR Diagnostics has developed ongoing, collaborative relationships with both academic institutions and private companies around the world to advance the discovery of objective measures of brain health

during injury and recovery. FYR currently has three employees. They are currently in discussion with an angel group for seed funding of \$500,000–\$1M.

- FYR Diagnostics is developing partnerships and collaborations with multiple companies to deploy the miRNA technology in research studies and potential clinical trials,
  - *VirtualMind LLC, Missoula, MT.* Co-developing virtual reality cognitive assessment solutions paired with miRNA diagnostics for TBI.
  - *Cortical Metrics LLC, Semora, NC.* Paring the Brain Gauge technology with miRNA detection.
  - *Tetra Discovery Partners, Inc., Grand Rapids, MI.* Development of Phosphodiesterase (PDE) modulators as potential therapeutics for TBI.
  - *Impact Technologies Australia Pty Ltd.* Quantifying head biomechanics in American collegiate football players at the University of Montana. Using the NEXUS A9 mouth guard to measure head impacts and investigate correlations with miRNA.
  - *Tonix Pharmaceutical, New York, NY.* Informal discussion to establish potential collaboration on TBI related projects in the future.
  - Established with Dr. Bill S. Rosen, MD, PC to providing subject consults for trials.
- Grants awarded to FYR
  - *Diagnosis of blast and impact traumatic brain injury using micro RNA biomarkers with virtual reality cognitive testing.* Montana Board of Research and Commercialization Technology (MBRCT). August 2017-July 2018; PI's Dr. Sarjubhai Patel, FYR Diagnostics, LLC & Dr. Erik Guzik, VAST Learning Solutions. **\$187,475** total costs.
- Grants submitted by FYR
  - *Diagnosis of blast and impact traumatic brain injury using micro RNA biomarkers with virtual reality cognitive testing.* Submitted April 2017, NIH NINDS R44; PI Dr. Thomas F. Rau, FYR Diagnostics, LLC. Funds requested **\$1.725 million**.
  - *Sex-linked differences in miRNA expression following following TBI.* Submitted June 2017, DoD Defense Medical Research and Development Program (DMRDP) JP-6; PI Dr. Thomas F. Rau, FYR Diagnostics, LLC. Funds requested **\$690,000**.

### Objective 3

- FYR Diagnostics, LLC is evaluating the novel TBI therapeutics and continuing to investigate the molecular mechanism involved in chronic traumatic encephalopathy (CTE).

## Objective 4



VAST Learning Systems has created two spin off companies and created new research opportunities,

- *VirtualMind, LLC* created to commercialize VR technology. VirtualMind is currently funded for ongoing research and development in 2017-18 and is actively engaged in additional grant and private funding for 2018-2019. VirtualMind will be piloted with 1 collegiate and 2 high school sports teams in Fall 2017, with negotiations proceeding for adoption among select Australian sports teams beginning in Spring 2018.
- *PatientOne, LLC* created indirectly through collaboration with project partners and community outreach. PatientOne informed consent software is currently being piloted in 5 test practices, with plans to expand to 50 Urology offices in Fall 2017.
- VAST will participate in a 3-year research program running from October 2017 through September 2020 led by Dr. Rex Jung at the University of New Mexico to introduce CogFit, its frontal lobe diagnostic software, into a long-term clinical trial.
- 4 private partnerships have been formed,
  - FYR Diagnostics, LLC
  - HitIQ (AUS)
  - Senso-Motoric Instruments (SMI)
  - Tobii Technology, Inc.
- 1 public partnership with Dr. Jung and the University of New Mexico.
- Full U.S. patent and related PCT for VR technology now under review by USPTO.
  - U.S. Patent Application No. 15/645,241  
Title: DIAGNOSING BRAIN INJURY USING A VIRTUAL REALITY SYSTEM  
Filed: July 10, 2017  
Inventor(s): Erik E. Guzik  
Applicant(s): VirtualMind, LLC
  - International Patent Application No. PCT/US2017/041779  
(Claiming priority to U.S. Patent Application No. 15/645,241)  
Title: DIAGNOSING BRAIN INJURY USING A VIRTUAL REALITY SYSTEM  
Filed: July 12, 2017  
Inventor(s): Erik E. Guzik  
Applicant(s): VirtualMind, LLC
- 3 total products developed and now being commercialized through MREDI funding:
  - VirtualMind VR Cognitive Assessment Platform
  - VastAbility Cognitive Training System

- CogFit Frontal Lobe Testing Software
- 1 private sector project management position and 2 private sector programming positions created in Missoula, with projections for 6-8 additional positions in the next 12-24 months.
- Total additional grants received
  - MBRCT grant for **\$187,475.00** received for VirtualMind testing with FYR Diagnostics, LLC.
- Total additional grants in progress
  - DoD DMRDP grant for **\$690,000** in submission with FYR Diagnostics, LLC.

## Objective 5



N-SITE, LLC continues to pursue validation of the PTE predictive EEG biomarker signals.

- N-Site created novel methods of analyzing big data sets that has relevance and applicability in the analysis of very large diagnostic data files which can be applied to a range of neurological disorders.
- N-Site has formed numerous research collaborations to deploy this technology.
  - In an active collaboration with Dr. Brian Steele and graduate students at the University of Montana mathematics department, the N-Site team created a novel data analysis and management system to analyze EEG trace recording and identify brain injured individuals that are 'at-risk' for the development of post-traumatic epilepsy.
  - N-Site is actively collaborating with Expesicor, a Montana company that is working in the epilepsy field to further advance the technology developed in this objective.
  - Working with Dr. Brandon Westover, M.D., Ph.D., Massachusetts General, and Harvard University on EEG project.
- N-Site is working to acquire an additional **\$250,000.00** in grants through Providence Health and Services.
- N-Site is aggressively pursuing private investment to develop the EEG signature technology.

## Final Metrics

- **Total additional grants received**
  - Match funding from N-Site \$350,000
  - Match funding from VAST \$65,000
  - GE/NFL award \$500,000
  - CTR-IN grants \$131,000
  - MBRCT \$187,475
  - AHRQ/UW \$6,300
  - ITHS CTSA \$30,000
  - \$1,269,775**
  
- **Total additional grants in progress**
  - Grants submitted or in preparation **\$4,115,000**
  
- **Number of partnerships formed (private and public sector)**
  - Private partnerships **13**
  - Public partnerships **10**
  
- **Number of new Montana businesses created** **5**
  
- **Patents awarded or in progress** **7**
  
- **Commercial products developed** **6**
  
- **Jobs created**
  - Private sector **12**
  - Administration **5**
  - Research Scientists **4**
  - Faculty-Biostatistician & Mathematician **2**
  - Technicians **2**
  - Students **3**
  - Post-docs **1**
  - Software Programmers **2**
  - Neuropsychologist **1**