AWARD NUMBER: W81XWH-22-1-0491

TITLE: Predicting ALS Outcomes Based on Networked Passive Sensors

PRINCIPAL INVESTIGATOR: William E. Janes, OTD, MSCI

CONTRACTING ORGANIZATION: The Curators of the University of Missouri Columbia, MO 65211-0001

REPORT DATE: JULY 2023

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
JULY 2023	Annual	06/15/2022-06/14/2023

4. TITLE AND SUBTITLE

Predicting ALS Outcomes Based on Networked Passive Sensors

5a. CONTRACT NUMBER
W81XWH-22-1-0491

5b. GRANT NUMBER
AL210017

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER
0011736304

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

The Curators of the University of Missouri
Office of Sponsored Programs Administration
601 Turner Avenue Garage, Room 201
Columbia, MO 65211-0001

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The purpose of the current project is to adapt an existing sensor-based alert system to facilitate early detection of physiological and functional declines among people living with ALS. The current project is a single-site pre-clinical trial to establish the feasibility and preliminary efficacy of the system and to establish a machine learning algorithm for predicting adverse health outcomes based on observed biometric data in people with ALS. Several logistical and regulatory challenges delayed recruiting for the project and subsequent recruiting efforts have been slower than expected. This Annual Technical Report explains steps taken and steps planned to increase recruitment. The Report also outlines progress to date in creating the machine learning algorithm that will be used to analyze data. One manuscript is preparation with intent to submit for publication in 2023. Data collection and analysis are ongoing.

15. SUBJECT TERMS

NONE LISTED

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
U	U	U	UU	42	19b. TELEPHONE NUMBER *(include area code)*

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1. **Introduction:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research*
   The **subject** and long-term goal of this work is to optimize multidisciplinary ALS care to slow the physiological and functional declines associated with ALS progression, prolong independence, and maintain quality of life. The **purpose** of the current project is to adapt an existing sensor-based alert system to facilitate early detection of physiological and functional declines among people living with ALS. The current project is a single-site pre-clinical trial to establish the feasibility and preliminary efficacy of the system and to establish a machine learning algorithm for predicting adverse health outcomes based on observed biometric data in people with ALS.

2. **Keywords:** *Provide a brief list of keywords (limit to 20 words). ALS, sensors, monitoring, machine learning, prediction*

3. **Accomplishments:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.*
   - What **were the major goals of the project?**

Major Goal	Target Date	% Complete / Completion Date
1a: Prepare regulatory documents and research protocols *Milestones:* *IRB Approval* *HRPO Approval*	31 August 2022	100% *12 April 2022* *3 May 2022*
1b: Operationalize data collection and prepare study infrastructure *Milestones:* *Functioning data collection pipeline that incorporates in-home and wearable sensor data and EHR outcomes data*	31 August 2022	100% *10 March 2023*
1c: Recruit participants and conduct feasibility and preliminary efficacy study *Milestone(s):* *Collection of feasibility data* *Publication of 1-2 papers* *Submission of 1-2 conference abstracts*	31 January 2024	1%
1d: Establish preliminary efficacy of the enhanced sensor system and unsupervised machine learning approach for detecting health changes in people with ALS *Milestone(s):* *Identification of machine learning features* *Publication of 1-2 papers* *submission of 1-2 conference abstracts*	31 August 2023	10%
2a: Train machine learning algorithm on training phase (12 month) data	31 December 2023	0%
2b: Test algorithm against validation phase (6 month) data *Milestones:* *Peer-reviewed publication of a validated model for predicting adverse health outcomes in ALS based on biometric data collected from passive in-home and wearable sensors* *NIH R01 grant application.*	30 June 2024	0%

   - **What was accomplished under these goals?**
     - 1a: Prepare regulatory documents and research protocols
       Local IRB approval was received 12 April 2022. While preparing study infrastructure (1b), we realized that

EHR data elements were all date-stamped, necessitating several IRB addenda. Those addenda triggered additional reviews. HRPO approval was received 3 May 2022.

- 1b: Operationalize data collection and prepare study infrastructure
  The research team met with ALS clinic staff to operationalize desired biomarkers and cross-walk with available sensor data and EHR data. The EHR data extraction tool was finalized and tested. Garmin smartwatch data were integrated into the server pipeline. Sensor data collection system was tested. In-home sensor systems and Garmin smartwatch devices were purchased. Anonymous user accounts were created for Garmin smartwatch devices. Additional study infrastructure (e.g. tracking spreadsheets, site visit documentation, etc.) was established.

- 1c: Recruit participants and conduct feasibility and preliminary efficacy study
  Recruitment has not progressed as expected. To date, one participant has consented to installation of the in-home sensor system. Data collection is ongoing with that participant. Recruiting difficulties and mitigation strategies are described in more detail in "Changes/Problems" below. Work on the feasibility manuscript(s) has been delayed pending recruitment.

- 1d: Establish preliminary efficacy of the enhanced sensor system and unsupervised machine learning approach for detecting health changes in people with ALS
  Data collection is ongoing. The research team has begun constructing the unsupervised machine learning model, described in section **6. Products / Technologies or techniques**, below.

- 2a: Train machine learning algorithm on training phase (12 month) data
  Training phase data collection is ongoing.

- 2b: Test algorithm against validation phase (6 month) data
  No validation phase data have been collected to date.

- **What opportunities for training and professional development has the project provided?**
  - Nothing to Report.
- **How were the results disseminated to communities of interest?**
  - Nothing to Report.
- **What do you plan to do during the next reporting period to accomplish the goals?**
  - Our most pressing plans are in the area of recruiting. We plan to work with ALS clinic staff to increase recruitment. We have also applied for research capacity funds from the ALS Association to reduce barriers to recruitment (details in Changes/Problems, below). The research team will continue regular meetings to monitor data collection, develop the machine learning algorithm, and progress with analysis and writing.

4. **Impact:** *Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*
   - **What was the impact on the development of the principle discipline(s) of the project?**
     - Nothing to Report.
   - **What was the impact on other disciplines?**
     - Nothing to Report.
   - **What was the impact on technology transfer?**
     - The project is likely to make an impact on the collection and integration of federated sensor and EHR data in ALS. The methods developed so far create new opportunities for post-hoc machine learning analyses of sensor and EHR data to predict adverse health outcomes. Although real-time monitoring and prediction are beyond the scope of this study, the methods developed so far prepare the path forward for that monitoring in future phases of this work. This represents the first application of the in-home sensor system to monitoring people living with ALS.
   - What was the impact on society beyond science and technology?
     - The project is likely to make an impact on independence and quality of life of people living with ALS. Specifically, the methods developed so far will directly contribute to future phases of this work focused on

real-time monitoring and prediction, with the intent of slowing the physiological and functional declines associated with ALS progression, prolonging independence, and maintaining quality of life

5. **Changes/problems:** *The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

- **Changes in approach and reasons for change**
  - We have quadrupled our recruiting area (from 7,854mi^2 to 31,416mi^2) to increase the sampling frame. The reason for this change is to increase opportunities for recruitment.
  - We have obtained clinic permission and IRB approval to recruit participants over the phone rather than in-clinic. No inclusion/exclusion criteria or other recruiting methods were affected by this change. The reason for this change was to reduce burden on clinic patients with the goal of increasing recruitment. The number of research projects in the clinic has increased dramatically since this project was conceived. Patients spend hours in clinic and are often exhausted before they are approached about research studies. We anticipate that this change will increase our recruiting yield.
  - We have added monthly collection of the ALS Functional Rating Scale (ALS-FRS) to the protocol. The ALS-FRS is the gold standard for clinical rating of ALS symptoms. We believe that this additional data point may be an important contributor to the machine learning model. We also anticipate that the sensor data may be able to provide an analog for ALS-FRS score that is useful in the future.
- **Actual or anticipated problems or delays and actions or plans to resolve them**
  - Recruiting has been the primary concern. Current actions to address recruiting are addressed in "Changes in approach…" above. Additionally, we have applied for research capacity funds from the ALS Association to reduce barriers to recruitment. If awarded, the ALS Association Research Capacity award would allow the neuromuscular clinic to hire a Research Coordinator to organize and facilitate recruiting across all studies in the clinic. This position would not replace the research coordinator on the current study. Rather, it would augment that position to reduce competition for potential participants.
  - Initial regulatory approval (IRB) went smoothly, but subsequent addenda caused delays. The EHR system date-stamps all data, which necessitated elevated data type permissions. These addenda took longer than anticipated to approve. The delay has been resolved.
  - Procurement of the sensor system took longer than anticipated due to institutional approval processes and supply chain disruptions. The delay has been resolved.
  - We encountered several unanticipated problems with the Garmin smartwatch. After successful in-house testing, the first watch deployed to a participant failed to upload data and failed to adjust to Daylight Saving Time. The data collection code had to be re-written and the watch re-provisioned. This problem has been resolved.
- **Changes that had a significant impact on expenditures**
  - None
- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**
  - There have been no significant deviations, unexpected outcomes, or changes in approved protocols. Institutional Review Board approval dates are as follows:
    12 April 2022
    10 August 2022
    24 October 2022
    15 February 2023
    18 May 2023
    12 June 2023
- **Significant changes in use or care of human subjects**
  - None
- **Significant changes in use or care of vertebrate animals**
  - None
- **Significant changes in use of biohazards and/or select agents**
  - None

6. **Products:** *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*
    - **Publications, conference papers, and presentations:** Report only the major publication(s) resulting from the work under this award.
        - **Journal publications**
            - None
        - **Books or other non-periodical, one-time publications**
            - None
        - **Other publications, conference papers, and presentations**
            - None
    - **Website(s) or other Internet site(s)**
        - None
    - **Technologies or techniques**

      We have begun creation of the machine learning model and the analysis pipeline. The initial analysis technique is described below.

      Sequential Possibilistic Gaussian Mixture Models (SPGMM) is a multi-dimensional streaming clustering algorithm developed for detecting changes in health parameters collected through in-home sensor data streams. The sensor streams are generated by three sensor types: bed, gait, and motion. SPGMM extends the sequential possibilistic one-means algorithm (SP1M) by using gaussian mixture models for tracking an individual's health trajectories, which are then evaluated for health warning conditions such as a negative trend or trajectories headed towards the cluster boundary in feature space. The health warning conditions will be validated against participant EHR records by date to measure correlation of the generated warnings with documented health events. Currently, recruitment has allowed for in-home sensor installation within a single ALS patient's home, which will serve as a case study for developing our analysis pipeline from sensor data collection to generated health warnings.

      The analysis pipeline is composed of multiple stages. Collected data are first preprocessed for deriving a set of features from each data type. Pulse rate, respiration rate, and sleep restlessness are derived from the bed sensor data. The depth sensor generates gait features for walking speed, stride length, and stride time. Motion sensors are aggregated by room location and motion duration. The derived features are then averaged over daily 24-hour periods and merged into a single matrix composing the feature space. SPGMM clustering is initially applied sequentially on each daily row of the matrix on the first 30 days of collected data to define the first cluster and any outliers. After model initialization, the model is updated as new daily feature aggregates become available and checked for new cluster formations and health trends. When a warning condition occurs, determined as the number of days that the participant's health trajectory is determined to be an outlier from the current cluster where low is a single day and high is 3 or more days, a warning is generated and stored by severity and date.

      Experimentally, we will initialize the SPGMM model and apply sequential clustering to all retrospective data collected for the current ALS participant. Generated warnings will then be matched by date to EHR records including new diagnoses, medication changes, and provider notes, which serve as ground truth for validating the SPGMM model outputs. We will then continue to generate warnings and validate against EHR data as records become available, prospectively.

    - **Inventions, patent applications, and/or licenses**
        - None
    - **Other products**
        - None
7. **Participants and collaborating organizations**
    - **What individuals have worked on this project?**

Name:	*William E. Janes*
Project Role:	*Principal Investigator*
Researcher Identifier (e.g. ORCID ID):	*0000-0002-6502-8130*
Nearest person month worked:	*2.0*

Contribution to Project:	*Dr. Janes has overseen all aspects of the project, including personnel management, data collection, data analysis, writing, and regulatory correspondence.*
Funding Support:	

Name:	*Vovanti Jones*
Project Role:	*Co-Investigator*
Researcher Identifier (e.g. ORCID ID):	*0000-0003-4402-1471*
Nearest person month worked:	*0.6*
Contribution to Project:	*Dr. Jones has overseen recruitment and coordination with the ALS clinic. Dr. Jones has contributed to the operationalization of biomarkers and outcomes.*
Funding Support:	

Name:	*Abu Mosa*
Project Role:	*Co-Investigator*
Researcher Identifier (e.g. ORCID ID):	*0000-0002-8956-1466*
Nearest person month worked:	*0.6*
Contribution to Project:	*Dr. Mosa has directed the contributions of NextGen Biomedical Informatics Center for the operationalization, linking, extraction, and verification of outcomes data from the EHR. He has also provided crucial insight into navigating complex IRB issues.*
Funding Support:	

Name:	*Mihail Popescu*
Project Role:	*Co-Investigator*
Researcher Identifier (e.g. ORCID ID):	*0000-0002-6145-8096*
Nearest person month worked:	*0.3*
Contribution to Project:	*Dr. Popescu has contributed to the plan for the initial algorithm and has overseen sensor database structure to ensure interoperability with the clinical dataset.*
Funding Support:	

Name:	*Marjorie Skubic*
Project Role:	*Co-Investigator*
Researcher Identifier (e.g. ORCID ID):	*0000-0002-3801-7639*
Nearest person month worked:	*0.3*

Contribution to Project:	*Dr. Skubic has overseen all activities in the Center for Eldercare and Rehabilitation Technology, including creation of the study database, assignment and supervision of staff to maintain the server, and facilitation of the sensor system purchase.*
Funding Support:	

Name:	*Xing Song*
Project Role:	*Co-Investigator*
Researcher Identifier (e.g. ORCID ID):	*0000-0002-3712-2904*
Nearest person month worked:	*2.0*
Contribution to Project:	*Dr. Song has led development of the predictive algorithm, including creating the federated process for importing data into the analysis platform and guiding data formatting to ensure interoperability.*
Funding Support:	

Name:	*Juliana Earwood*
Project Role:	*Research Coordinator*
Researcher Identifier (e.g. ORCID ID):	*0000-0002-2694-4486*
Nearest person month worked:	*5.0*
Contribution to Project:	*Mrs. Earwood maintains all regulatory compliance documentation, coordinates the activities of all study team members, assists in recruitment, and conducts all evaluations.*
Funding Support:	

Name:	*Zachary Selby*
Project Role:	*Software Support Analyst - Specialist*
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	*5.0*
Contribution to Project:	*Mr. Selby installs and maintains the sensor systems. This includes routine monitoring of data collection, troubleshooting, and maintaining inventory of sensor components.*
Funding Support:	

- **Has there been a change in the active other support of the PD/PIs or senior/key personnel since the last reporting period?**
    - Other Support documents for Senior/key personnel are included as appendices, with highlights indicating changes since the original grant submission.
- **What other organizations were involved as partners?**
    - Nothing to Report.

8. **Special Reporting Requirements**
   - **Quad Chart:** Attached.

9. **Appendices**

Appendix A. Updated "Other Support" documents for senior/key personnel. (Begins on next page)

SUPPORT
JANES, WILLIAM E

Previous
Title: Comparative effectiveness of a virtual reality platform for neurorehabilitation of hemiparesis.
Time Commitments: 1.2 calendar
Supporting Agency: Patient-Centered Outcomes Research Institute (PCORI) AD-1409-20,772
Address: 1828 L Street NW, Suite 900, Washington, DC 20036
Contracting/Grants Officer: Chad C. Harper
Performance Period: 9/1/18-12/31/19
Level of funding:
Project Goals: The goal of this project is to provide information to therapists and patients/families regarding the relative effectiveness of four potential treatment alternatives for chronic hemiparesis; traditional constraint-induced (CI) therapy, therapist-as-consultant virtual reality CI therapy, telerehabilitation therapist-as-consultant virtual reality CI therapy, and 5 hours of standard care.
Specific Aims: The lower cost gaming therapy will be of comparable effectiveness to CI therapy and more effective than standard occupational therapy.
Overlap: No scientific or budgetary overlap with the proposed PRMRP proposal

Title: Reliability and validity testing of a data logging device for early childhood power mobility.
Time Commitments: .3 calendar
Supporting Agency: School of Health Professions Catalyst Award**.**
Address: 510 Lewis Hall, Columbia, MO 65211
Contracting/Grants Officer: Tammy Winfrey
Performance Period: 7/1/19-12/31/20
Level of funding:
Project Goals: The purpose of this study is to establish reliability and validity of an onboard instrumentation device to document use of early childhood power mobility devices for use in the lab setting and in the home.
Specific Aims: Aim 1: Establish test-retest reliability of the data logging device. Aim 2: Establish concurrent and ecological validity of the data logging device.
Overlap: No scientific or budgetary overlap with the proposed PRMRP proposal

Current
Title of project: Predicting ALS Outcomes Based on Networked Passive Sensors
Project Number: W81XWh2210491
Effort: 10%
Performance Period: 06/15/2022 – 06/14/2024
Supporting agency: Department of Defense
Supporting agency POC: USAMRDC Office of Research; help@eBRAP.org
Project Goals: The major goal of this project is to adapt the existing sensor-based alert system to facilitate early detection of physiological and functional declines among people living with ALS. We will first augment the sensor-based alert system with additional inputs from commercially-available wearable sensors to capture additional important biomarkers for ALS progression (e.g.: oxygen saturation, continuous pulse). We will train and validate our existing algorithms to predict adverse health outcomes (e.g.: hospitalization, pneumonia, death) in ALS based on changes in the biomarker data. We will test three hypotheses across two specific aims.
Specific aims: Aim 1: Establish feasibility and preliminary efficacy of an observational system for detecting clinical progression in people with ALS using networked home-based and wearable sensors. Aim 2: Establish a machine learning algorithm for predicting adverse health outcomes based on observed biometric data in people with ALS.
Overlap: [Current Project]

Title: Multisite Customizable Assistive Technology Intervention.
Time Commitments: 0 calendar

Supporting Agency: ALS Association
Address: 1300 Wilson Boulevard, Suite 600, Arlington, VA 22209
Contracting/Grants Officer: Neil Thakur
Performance Period: 12/1/2022 – 11/30/2023
Level of funding:
Project Goals: The goal of this project is to test the feasibility and preliminary efficacy of a multi-site customizable assistive technology intervention for people living with ALS.
Specific Aims: Evaluate the feasibility of a multi-site customizable AT intervention. Evaluate the efficacy of a multi-site customizable AT intervention.
Overlap: No scientific or budgetary overlap with the current proposal

SUPPORT
JONES, VOVANTI

Current
Title: Multimodal biomarker of neurodegenerative diseases affecting motor system – an integrative imaging and behavioral study
Supporting Agency: MU School of Medicine Translation Research Informing Useful and Meaningful Precision Health (TRIUMPH) Award
Address:
Office of Research and Economic Development
310 Jesse Hall
University of Missouri
Columbia, MO 65211
Contracting/Grants Officer: William P. Fay
Performance Period: 05/01/2021 – 04/30/2023
Level of Funding:
Project Goals: To identify motor system alterations' pattern (or neural signatures) of amyotrophic lateral sclerosis and Parkinson's disease at diagnosis and study how these alterations predict what will happen to the patient for the next six months after diagnosis. Data acquired in this cross-sectional study will provide evidence of a disease-specific biomarker, by focusing on knowledge gaps, namely identifying neural signature of each disease via the refine dissection of perturbations in cellular, molecular, and neurotransmitter systems in disease-targeted motor brain areas.
Specific Aims: To determine if we can predict rate of functional decline based on motor system alteration patterns in ALS and Parkinson's patients
Overlap: There is no overlap between the aforementioned proposals and the current proposal.

Title: MDA Care Center
Supporting Agency: Muscular Dystrophy Association Number: MDA Award ID 492683
Address:
161 N. Clark, Suite 3550
Chicago, Illinois 60601
Contracting/Grants Officer: Muscular Dystrophy Association Innovations in Care Grants
Performance Period: 01/01/2021-06/30/2022
Level of Funding:
Project Goals: To establish a multidisciplinary care team for patients with neuromuscular disorders including muscular dystrophy and amyotrophic lateral sclerosis. MDA's National Care Center Network serves as a hub of neuromuscular research activity and clinical trials. Research activities and clinical trial readiness across the Care Center Network will help increase access for individuals and families affected by neuromuscular disease to participate in appropriate research activities and clinical trials for which they may be eligible.
Specific Aims: To support the clinic and multidisciplinary team caring for patients with neuromuscular disorders
Overlap: There is no overlap between the aforementioned proposals and the current proposal.

Title: Amyotrophic Lateral Sclerosis Association Care Center Grant
Supporting Agency: ALS Association of America
Address:
6405 Metcalf Ave., Suite 205,
Overland Park, KS 66202
Contracting/Grants Officer: National Institutes of Health
Performance Period: 01/01/2022-12/31/2023
Level of Funding:

Project Goals: To establish a multidisciplinary care team for patients with amyotrophic lateral sclerosis

Specific Aims: To improve access to care for patients with ALS
Overlap: There is no overlap between the aforementioned proposals and the current proposal.

SUPPORT
MOSA, ABU SALEH MAHOMMAD

Current
Title: Greater Plains Collaborative Optimizing Infrastructure
Time Commitment: 1.2 calendar months
Supporting Agency: Patient Centered Outcomes Research Institute
Address: 1828 L St., NW, Suite 900, Washington, DC 20036
Contracting/Grants Officer: Claudia Grossmann, PhD
Performance Period: 01/01/2022 – 12/31/2024
Level of Funding:
Project Goal: Provide overall network leadership for the Greater Plains Collaborative (GPC) PCORNet Clinical Data Research Network (CRN) consisting of thirteen research medical centers. This effort will evolve and support a clinical research network infrastructure that captures complete and comprehensive data from patients at thirteen medical centers. This includes developing the governance, regulatory processes, technical infrastructure, and patient engagement strategies to enable a learning health care system by integrating Comparative Effectiveness Research with clinical workflows. Develop sustainable model for this digital infrastructure.
Specific Aims: The aims include developing the governance, regulatory processes, technical infrastructure, and patient engagement strategies to enable a learning health care system by integrating Comparative Effectiveness Research with clinical workflows. Develop sustainable model for this digital infrastructure.
Overlap: No overlap

Title of project: Predicting ALS Outcomes Based on Networked Passive Sensors
Project Number: W81XWh2210491
Effort: 0.6 calendar months
Performance Period: 06/15/2022 – 06/14/2024
Supporting agency: Department of Defense
Supporting agency POC: USAMRDC Office of Research; help@eBRAP.org
Project Goals: The major goal of this project is to adapt the existing sensor-based alert system to facilitate early detection of physiological and functional declines among people living with ALS. We will first augment the sensor-based alert system with additional inputs from commercially-available wearable sensors to capture additional important biomarkers for ALS progression (e.g.: oxygen saturation, continuous pulse). We will train and validate our existing algorithms to predict adverse health outcomes (e.g.: hospitalization, pneumonia, death) in ALS based on changes in the biomarker data. We will test three hypotheses across two specific aims.
Specific aims: Aim 1: Establish feasibility and preliminary efficacy of an observational system for detecting clinical progression in people with ALS using networked home-based and wearable sensors. Aim 2: Establish a machine learning algorithm for predicting adverse health outcomes based on observed biometric data in people with ALS.
Overlap: [Current Project]

Title: Washington University Institute of Clinical and Translational Sciences
Time Commitment: 1.2 calendar
Supporting Agency: National Institutes of Health
Address: 9000 Rockville Pike, Bethesda, Maryland 20892
Contracting/Grants Officer: Pending
Performance Period: 03/01/2023 – 02/29/2024
Level of Funding:
Project Goal: The Biomedical Informatics Component (BMIC) of Washington University (WU) Institute for Clinical and Translational Sciences (ICTS) will be a digital hub for clinical and translational researchers. The BMIC has four functions: (1) connecting investigators and trainees with data collection, management, analysis, and dissemination platforms and tools, (2) supporting the collaborative design and execution of data-intensive

research projects, (3) ensuring the security and interoperability of the data assets across our partner institutions and with the CTSA network, and (4) delivering tailored clinical and translational informatics education and workforce development programs.
Specific Aims: To satisfy the BMIC functions by leveraging a combination of component-specific personnel, technologies, and data assets, as well as complementary internal [e.g., WU and BJC HealthCare (BJC)] and external (e.g., CTSA shared resources) capabilities.
Overlap: No overlap

Title: The RECOVER Post-Acute Sequelae of SARS-CoV-2 (PASC) Electronic Health Record (EHR) Cohort Study
Time Commitment: 3.6 calendar months
Supporting Agency: Childrens Hospital of Philadelphia
Address: Roberts Ctr for Pediatric Research, 2716 South St., 17th Floor Philadelphia, PA 19146-2305Contracting/Grants Officer: Jeannine Voll
Performance Period: 10/01/2021 – 10/31/2023
Level of Funding:
Project Goal: The Adult PCORnet-PASC project will leverage the Patient-Centered Clinical Research Network (PCORnet®) for PASC data science research in adults. PCORI provides infrastructure support for PCORnet to maintain baseline network readiness in terms of common data elements, data quality, and stakeholder engagement. This research project provides additional funds to expand the core data elements, create a research ready data set, and engage researchers. This work will build off the COVID-19 CDC-funded PCORnet surveillance project, which engages 42 health systems to contribute data for epidemiological surveillance. In the CDC work, health systems retain ownership of a limited number of data elements that are queried centrally. To perform the data science that is required for the EHR/ORWD grantees, these data elements will need to be supplemented and centralized.
Specific Aims: In this project, a single, unified, PCORnet EHR/ORWD Repository will be developed that will support both the Adult and Pediatric PCORnet-PASC proposals, creating one large analytical database that spans children and adults. Once an analytical database is created, advanced machine learning methodologies will be employed to determine phenotypes including a screening phenotype for use by the RECOVER clinical cohorts, sub phenotypes, risk and mitigating factors, predictive models, and determine disparities. The project will cross-validate other phenotypes developed by other members of the Consortium and will satisfy all of the proposed deliverables within the proposed timeline.
Overlap: No overlap

Title: COVID19 Electronic Healthcare Data Initiative
Time Commitment: 1.5 calendar months
Supporting Agency: Public Health Informatics Institute
Address: 330 W. Ponce de Leon Ave, Decatur, Georgia 30030
Contracting/Grants Officer: Tonya Duhart, Sr. Business Manager
Performance Period: 10/01/2021 – 07/31/2023
Level of Funding:
Project Goal: PCORnet has been working actively to build infrastructure to support COVID-19 surveillance across PCORnet. Sites participating in the COVID-19 Electronic Healthcare Data Initiative have been refreshing their data on patients who have had SARS-CoV-2 testing and diagnostic codes for viral illness. For Year 2 of this project, sites will continue updating their data and responding to queries, along with working to enhance their data infrastructure to support querying of vaccine data.
Specific Aims: This funding will facilitate continued surveillance and population health research on topics that are identified as high priority areas by CDC and PCORnet, such as: • Characteristics of adults and children infected with COVID-19 and other infections, by geography and other designated subgroups • Trends in COVID-19 infections, especially unusual complications (e.g., pediatric multisystem inflammatory syndrome) and other rare outcomes; long-term sequelae of infection; use of COVID-19 treatments over time; use and outcome of vaccine administration over time • Predictive modeling of factors associated with disease severity,

especially demographic and clinical subgroups (e.g., racial disparities, outcomes by diabetes, obesity and use of immunosuppressive agents) • Trends in hospitalizations for other diseases during the COVID-19 pandemic, allowing for an assessment of whether delays in case might have led to poor outcomes
Overlap: No overlap

Pending

Title: Transfer Learning Based Neural Network Embedded Energy-Efficient Hardware Architecture Design for Sleep Apnea Detection
Time Commitment: 0.25 calendar months
Supporting Agency: National Institutes of Health
Address: 9000 Rockville Pike, Bethesda, Maryland 20892
Contracting/Grants Officer: Pending
Performance Period: 08/01/2023 – 07/31/2025
Level of Funding:
Project Goal: The proposal focuses on developing energy-efficient hardware architectures for sleep apnea screening devices among adults with integrated ECG and SpO2 biosensors as the front-end sensors.
Specific Aims: The hardware architecture leverages transfer learning based neural networks for automatic detection of sleep apnea resulting in the reduction of the workload of clinicians and caregivers.
Overlap: No overlap

Title: PCOG-90: PCORnet Study of Older Persons with Superior Cognitive Performance Over Age 90
Time Commitment: 0.6 calendar months
Supporting Agency: Tulane University
Address:
Contracting/Grants Officer: Pending
Performance Period: 12/01/2023 – 11/30/2028
Level of Funding:
Project Goal: Subcontract with Tulane on NIH U19 resubmission (PI - Demetrius Maraganore) The team proposes PCORnet study of older persons with superior cognitive performance over age 90 ("PCOG-90").
Specific Aims: 1) To mine existing EMR data relating to medical determinants of health, and link those data with newly collected social, cognitive, digital, and biological health data, and to evaluate factors including genetics, epigenetics, metabolism, the gut microbiome, immune function, environment, and lifestyle, to understand how they associate over time with successful cognitive and biological aging across the health span. 2) To conduct studies of superior cognitive performance in racially and ethnically diverse (including African American, Caucasian, and Hispanic) and geographically diverse (including rural and urban) aging populations nationwide.
Overlap: No overlap

Title: Scope 3: PCORnet® Designated Study Consultation and Query and Analytic Tool Development to Enable Multi-network PCORnet® Research
Time Commitment: 0.72 calendar months
Supporting Agency: Childrens Hospital of Philadelphia
Address: Roberts Ctr for Pediatric Research, 2716 South St., 17th Floor Philadelphia, PA 19146-2305
Contracting/Grants Officer: Pending
Performance Period: 01/01/2023 – 12/31/2024
Level of Funding:
Project Goal: Collaborate with Scope 3 Coordinating Center (CC) on PCORnet leadership Work with the Scope 3 CC at The Children's Hospital of Philadelphia (CHOP) to provide scientific and operational leadership to inform and guide the maintenance, enhancement, and evolution of the PCORnet distributed research network.
Specific Aims: Provide scientific and operational leadership to identify and support PCORnet Designated

Studies that are national in scope.
Overlap: No overlap

Title: Empowering patients to better understand their disease and responses to treatments
Time Commitment: 1.2 calendar
Supporting Agency: Patient Centered Outcomes Research Institute through the University of Miami
Address: 1828 L St., NW, Suite 900, Washington, DC 20036
Contracting/Grants Officer: Pending
Performance Period: 07/01/2021 – 06/30/2024
Level of Funding:
Project Goal: ALS is a neurodegenerative disorder that manifests primarily with progressive weakness of limb, bulbar and breathing muscles. It is an invariably fatal disorder with death, typically from respiratory failure, ensuing within 3-5 years of symptom onset. This study will address the following key clinical decision dilemmas that are foremost in patients' minds: (a) as a patient with ALS, PMA or PLS, how do I know if I stand to benefit from Riluzole, Edaravone, or an AOT that I have elected to use? (b) do I have an identifiable genetic cause of my disease that might makAIMSe me eligible to participate in one of several emerging gene therapies trials?
Specific Aims: We will implement and use the ALS Toolkit in clinic at the point of care to collect clinical information about ALS patients, and to document use of alternative and off label treatments (AOTs) as well as the results of clinical genetic testing. We will work with the PCORnet coordinating center to develop CDM tables to capture these critical data elements.
Overlap: No overlap

Title: Determining Best or Inferior Drugs Using an Adaptive Platform for Cryptogenic Sensory Polyneuropathy
Time Commitment: 1.8 calendar
Supporting Agency: Patient Centered Outcomes Research Institute
Address: 1828 L St., NW, Suite 900, Washington, DC 20036
Contracting/Grants Officer: Pending
Performance Period: 07/01/2024 – 12/31/2030
Level of Funding:
Project Goal: Cryptogenic sensory polyneuropathy (CSPN) is a common, but under recognized and understudied condition that is debilitating due to pain. We plan to study five drugs- topiramate, gabapentin, tramadol, levetiracetam, and valproate for CSPN treatment and estimate comparative effectiveness. These are all drugs are often used to treat painful peripheral neuropathy.
Specific Aims: To determine which drug is most effective in producing pain relief and improving quality of life in patients with CSPN. Also, engage primary care physicians in identifying, referring, and improving care of patients with CSPN. We would also like to determine which drug has the least amount of side effects and compare this data with the data found in the previous study.
Overlap: No overlap

Title: Acute Initial Medications for Spinal Osteoporotic Fracture Treatment (AIMSOFT)
Time Commitment: 1.2 calendar
Supporting Agency: Patient Centered Outcomes Research Institute through the University of Washington
Address: 1828 L St., NW, Suite 900, Washington, DC 20036
Contracting/Grants Officer: Pending
Performance Period: 11/01/2021 – 10/31/2026
Level of Funding:
Project Goal: Perform a pragmatic, randomized controlled trial comparing NSAIDs, calcitonin and opioids for initial treatment of pain after vertebral osteoporotic fractures
Specific Aims: To recruit patients prospectively and use PCORnet Common Data Model for EHR data study.
Overlap: No overlap

Title: SCH: A Data-Driven AI-Enabled Embedded System for Wearable Sleep Apnea Monitoring
Time Commitment: 1 calendar
Supporting Agency: National Science Foundation
Address: 2415 Eisenhower Avenue, Alexandria, Virginia 22314
Contracting/Grants Officer: Pending
Performance Period: 09/01/2021 – 08/31/2025
Level of Funding:
Project Goal: The objective of this project is to design a wearable, compact and energy efficient AI-enabled embedded biomedical system capable of automatic detection and monitoring of sleep apnea among adults. The proposed solution is a significant improvement over the current methods of diagnosis of sleep apnea which require expensive overnight sleep studies and subsequent manual scoring of the apneic events from the data requiring specially trained sleep experts. In the proposed design AI/machine learning models are simplified through quantization and pruning targeting 2x times reduction of network size prior to their implementation in the hardware. This method substantially reduces power dissipation and simplifies the electronic circuits making possible the realization of the hardware in standard CMOS process.
Specific Aims: To develop AI machine learning models and develop embedded system on chip for sleep apnea detection.
Overlap: No overlap

Title: The Midwest Center for Precision Nutrition
Time Commitment: 2.4 calendar
Supporting Agency: National Institutes of Health
Address: 9000 Rockville Pike, Bethesda, Maryland 20892
Contracting/Grants Officer: Pending
Performance Period: 12/01/2021 - 11/30/2026
Level of Funding:
Project Goal: The proposed study will identify genetic, environmental, and behavioral patterns that influence an individual's metabolic risk attributed to dietary intake. This research will provide new information to discover the factors that place individuals at risk for the development of chronic diseases, with the goal of developing individualized dietary strategies to reduce disease burden in the U.S.
Specific Aims: Specific aim 1 hypotheses: 1A) Phenotypes, behavioral/ environmental factors, microbial species, and blood metabolites will be identified that predict increases in lipid synthesis; 1B) Elevated lipids (measured via LC/MS) will be significantly related to current risk markers for T2D and CVD. Specific aim 2 hypotheses: 2A) For all subjects, postprandial lipid synthesis will be highest in diets that are either high-SF or high-sugar, and lowest in diets low in SF and sugar. 2B) Responders will be defined as participants who exhibit diet-induced elevations in fasting and postprandial lipids. 2C) Increased saturation of blood lipids will be associated with biomarkers of chronic disease.
Overlap: No overlap

Previous
Title: Missouri HIV Testing Integrated Database for the National HIV Prevention Program Monitoring and Evaluation
Time Commitments: 2.18 calendar
Supporting Agency: Missouri Department of Health and Senior Services
Address: 930 Wildwood Dr, Jefferson City, MO 65109
Contracting/Grants Officer: Venkata Garikapaty
Performance period: 10/01/2021-09/30/2022
Level of funding:
Project Goals: Missouri's HIV Prevention Program, housed in the Missouri Department of Health and Senior Services (MDHSS), ensures access to comprehensive HIV testing services that include counseling and linkage to HIV care for Missourians through a network of contracted providers throughout the state. The Missouri HIV Testing Database enables the incorporation of data-to-action processes by centralizing data collection from all

Missouri HIV testing contractors. Data collected are also be de-identified and securely transmitted to the Centers for Disease Control and Prevention via Evaluation Web a CDC-sponsored online data collection and reporting system specifically for HIV testing and prevention activities, and used to inform funding decisions and monitor program quality measures. We will develop and construct a REDCap tool to collect all required and mandatory fields as described in the CDC's National Data Variables & Values documentation and any additional fields that are needed to support the MDHSS's operational procedure.
Specific Aims: The database will incorporate considerations for contracted HIV testing providers across the State of Missouri: a) providers will have access in order to manually enter or electronically import from electronic health record (EHR) systems their patient testing information; b) providers will not have access to any Missouri HIV Testing Database information that originates outside of their facility or subcontracted site(s); and c) providers will be able to access facility-level data reports.
Overlap: No overlap

Title: Non-small Cell Lung Cancer (NSCLC): Automation of Clinical Data Extraction Using Natural Language Processing Techniques for Enhanced Data Analytics, Patient Journeys, and Patient Clusters
Time Commitments: 3.0 calendar
Supporting Agency: Roche Molecular Systems Inc.
Address: 1301 Shoreway Road, Suite 300, Belmont, CA 94002
Contracting/Grants Officer: Vishakha Sharma
Performance period: 10/01/2019-09/30/2022
Level of funding:
Project Goals: In the first phase of the project for creating a patient journey and timeline dashboard, we used structured data and extracted clinical information from the unstructured data by manual curation. Manual curation is a time-consuming and costly process. Manual process is a big obstacle for taking the full potential for automatic data abstraction and using such data in clinical decision making tools. The goal was to use unstructured clinical notes for creating an enhanced patient journey and timeline dashboard.
Specific Aims: The objective of this project is to apply the natural language processing (NLP) techniques for semi-automated de-identification and automatic extraction of clinical data from the unstructured data for enhancement of the patient journey and timeline dashboard.
Overlap: No overlap

Title: Advancement of PCORnet Infrastructure: Clinical Research Network
Time Commitments: 3.0 calendar
Supporting Agency: Patient Centered Outcomes Research Institute (PCORI)
Address: 1828 L St., NW, Suite 900, Washington, DC 20036
Contracting/Grants Officer: Claudia Grossmann, PhD
Performance Period: 10/01/2020 – 12/31/2021
Level of funding:
Project Goals: Provide overall network leadership for the Greater Plains Collaborative (GPC) PCORNet Clinical Data Research Network (CRN) consisting of thirteen research medical centers. This effort will evolve and support a clinical research network infrastructure that captures complete and comprehensive data from patients at thirteen medical centers.
Specific Aims: The aims include developing the governance, regulatory processes, technical infrastructure, and patient engagement strategies to enable a learning health care system by integrating Comparative Effectiveness Research with clinical workflows. Develop sustainable model for this digital infrastructure.
Overlap: No overlap

Title: Using PCORnet to Compare Blood Pressure Control Strategies
Time Commitments: 0.30 calendar
Supporting Agency: Patient Centered Outcomes Research Institute (PCORI) through Duke University
Address: 1828 L St., NW, Suite 900, Washington, DC 20036
Contracting/Grants Officer: Claudia Grossmann, PhD

Performance period: 10/20/2019-05/31/2023
Level of funding:
Project Goals: In collaboration with the American Heart Association (AHA) and the American Medical Association (AMA), the Health eHeart Alliance and PCORnet Cardiovascular Health Collaborative Research Network propose to establish the National Blood Pressure Control Laboratory to enhance cardiovascular health and blood pressure control in the US.
Specific Aims: To enable blood pressure control surveillance, provide feedback to healthcare systems and clinicians, and conduct efficient pragmatic comparative effectiveness research on interventions designed to enhance blood pressure control.
Overlap: No overlap

Title: Evaluation and Improvement of Data Quality in Missouri's Immunization Information System for COVID19 Related Vaccination Reporting
Time Commitments: 2.4 calendar
Supporting Agency: Missouri Department of Health and Senior Services
Address: 930 Wildwood Dr, Jefferson City, MO 65109
Contracting/Grants Officer: Venkata Garikapaty
Performance period: 06/01/2021 – 05/31/2022
Level of funding:
Project Goals: The goals of this agreement are to help the Missouri Department of Health and Senior Services (MDHSS) improve data quality in the ShowMeVax (WebIZ vendor) system and improving unidirectional and bidirectional data transmission between the system and data providers
Specific Aims: Programming for quality and maintenance of the Missouri vaccine data system
Overlap: No overlap

Title: Identifying Personalized Risk of Acute Kidney Injury with Machine Learning
Time Commitment: 0 calendar
Supporting Agency: National Institute of Health through the University of Kansas Medical Center Research Institute
Address: 9000 Rockville Pike, Bethesda, Maryland 20892
Contracting/Grants Officer: Ivonne Hernandez Schulman
Performance Period: 09/01/2019-09/30/2022
Level of Funding:
Project Goal: The ability to predict Acute Kidney Injury (AKI) in hospitalized patients would provide clinicians the opportunity to modify care pathways and implement interventions, which could in turn prevent AKI and yield better outcomes. The goal of the project is to analyze EHR data on ICU and general inpatient populations to gain knowledge of AKI risk factors, characterized by numerous deficiencies and systematic failings that may be avoidable to transform the reactive AKI care to proactive and personalized care, early identification of high risk patients and better understanding of individual modifiable risk factors for AKI is the key.
Specific Aims: This project aims to address three critical clinical questions: (1) who are the high-risk patients for developing acute kidney injury (AKI) in the hospital?, (2) what are the modifiable risk factors of AKI to avoid for the high-risk population?, and (3) what are the specific risk factors of AKI to avoid for an individual patient?
Overlap: No overlap

Title: Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-term Effectiveness (ADAPTABLE)
Time Commitment: 0 calendar
Supporting Agency: Patient Centered Outcome Research Institute through University of Kansas Medical Center Research Institute

Address: 1828 L St., NW, Suite 900, Washington, DC 20036
Contracting/Grants Officer: Claudia Grossmann, PhD
Performance Period: 02/28/17 – 03/31/21
Level of Funding:
Project Goal:. To identify the optimal dose of aspirin for secondary prevention in patients with ASCVD, we are participating in a pragmatic clinical trial in which 20,000 patients who are at high risk for ischemic events will be randomly assigned in a 1:1 ratio to receive an aspirin dose of 81 mg/day vs. 325 mg/day. Study participants will be enrolled over 24 months. Maximum follow-up will be 30 months.
Specific Aims: The primary endpoint is a composite of all-cause death, hospitalization for MI, or hospitalization for stroke. The primary safety endpoint is hospitalization for major bleeding with an associated blood product transfusion.
Overlap: No overlap

Title: DHSS Home Visiting Program/Maternal Infant and Early Childhood-Integrated Data System: REDCap v2.0
Time Commitment: 2.4 calendar
Supporting Agency: Missouri Department of Health & Senior Services
Address: 930 Wildwood Dr, Jefferson City, MO 65109
Contracting/Grants Officer: Venkata Garikapaty
Performance Period: 10/01/15 – 09/30/16
Level of Funding:
Project Goal: The goal of this project is to develop a data collection system for the Missouri Department of Health and Senior Services (DHSS) Maternal and Child Health Home Visiting Programs which are funded by the United States Department of Health and Human Services. The system is used by the public health workers at the local implementing agencies across the State of Missouri, which is a secure, central and completely online system.
Specific Aims: To develop and maintain an electronic data capture system using the REDCap platform.
Overlap: No overlap

Title: DHSS Home Visiting Program/Maternal Infant and Early Childhood-Integrated Data System: REDCap v2.0
Time Commitments: 3 calendar
Supporting Agency: Missouri Department of Health & Senior Services
Address: 930 Wildwood Dr, Jefferson City, MO 65109
Contracting/Grants Officer: Venkata Garikapaty
Performance Period: 10/01/16 – 09/30/17
Level of Funding:
Project Goal: The goal of this project is to develop a data collection system for the Missouri Department of Health and Senior Services (DHSS) Maternal and Child Health Home Visiting Programs which are funded by the United States Department of Health and Human Services. The system is used by the public health workers at the local implementing agencies across the State of Missouri, which is a secure, central and completely online system.
Specific Aims: To develop and maintain an electronic data capture system using the REDCap platform.
Overlap: No overlap

Title: Birth Defect Research Electronic Data Capture System
Time Commitment: 1.2 calendar
Supporting Agency: Missouri Department of Health & Senior Services
Address: 930 Wildwood Dr, Jefferson City, MO 65109
Contracting/Grants Officer:
Performance Period: 06/01/18 – 01/31/19
Level of Funding:

Project Goal: In this project we have developed a research electronic data capture system to be used by the Missouri Department of Health and Senior Services in order to facilitate secure online data collection. The system is used by the US Zika Pregnancy and Infant Registry program staffs at the Missouri DHSS.
Specific Aims: To develop and maintain an electronic data capture system using the REDCap platform.
Overlap: No overlap

Title: DHSS Home Visiting Program/Maternal Infant and Early Childhood-Integrated Data System: REDCap v2.0
Time Commitment: 3 calendar
Supporting Agency: Missouri Department of Health & Senior Services
Address: 930 Wildwood Dr, Jefferson City, MO 65109
Contracting/Grants Officer: Venkata Garikapaty
Performance Period: 10/01/17 – 09/30/18
Level of Funding:
Project Goal: The goal of this project is to develop a data collection system for the Missouri Department of Health and Senior Services (DHSS) Maternal and Child Health Home Visiting Programs which are funded by the United States Department of Health and Human Services. The system is used by the public health workers at the local implementing agencies across the State of Missouri, which is a secure, central and completely online system.
Specific Aims: To develop and maintain an electronic data capture system using the REDCap platform.
Overlap: No overlap

Title: Building Patient Centered Outcomes Research Capacity: Care Transitions
Time Commitment: 1.2 calendar
Supporting Agency: Agency for Healthcare Research and Quality (AHRQ)
Address: 5600 Fishers Lane, Rockville, MD 20857
Contracting/Grants Officer: Jennifer E Moore
Performance Period: 09/30/17 – 09/29/19
Level of Funding:
Project Goal: The goal of MU Center for PCOR was to develop capacity to conduct research and disseminate results related to transitions patients experience from one site of care to another, such as hospital to home, or from one phase of care to another, such as initiating opioids to treat chronic pain.
Specific Aims: The grant includes three research projects and core activities focused on improving capabilities in using large data sets to conduct comparative effectiveness research and on facilitating practice and system change. There is a partnership with the American Academy of Family Physicians National Research Network.
Overlap: No overlap

Title: DHSS Home Visiting Program/Maternal Infant and Early Childhood-Integrated Data System: REDCap v2.0
Time Commitment: 3 calendar
Supporting Agency: Missouri Department of Health & Senior Services
Address: 930 Wildwood Dr, Jefferson City, MO 65109
Contracting/Grants Officer: Venkata Garikapaty
Performance Period: 10/01/18 – 09/29/19
Level of Funding:
Project Goal: The goal of this project is to develop a data collection system for the Missouri Department of Health and Senior Services (DHSS) Maternal and Child Health Home Visiting Programs which are funded by the United States Department of Health and Human Services. The system is used by the public health workers at the local implementing agencies across the State of Missouri, which is a secure, central and completely online system.
Specific Aims: To develop and maintain an electronic data capture system using the REDCap platform.
Overlap: No overlap

Title: DHSS Zika Pregnancy Registry and Birth Defects Surveillance of Missouri - YEAR 2
Time Commitment: 1.2 calendar
Supporting Agency: Missouri Department of Health & Senior Services
Address: 930 Wildwood Dr, Jefferson City, MO 65109
Contracting/Grants Officer: Venkata Garikapaty
Performance Period: 02/01/19 – 10/31/19
Level of Funding:
Project Goal: In this project we have developed a research electronic data capture system to be used by the Missouri Department of Health and Senior Services in order to facilitate secure online data collection. The system is used by the US Zika Pregnancy and Infant Registry program staffs at the Missouri DHSS.
Specific Aims: To develop and maintain an electronic data capture system using the REDCap platform.
Overlap: No overlap

Title: A National Report of Nursing Home Quality Measures and Information Technology.
Time Commitment: 1.2 calendar
Supporting Agency: Agency for Healthcare Research and Quality (AHRQ)
Address: 5600 Fishers Lane, Rockville, MD 20857
Contracting/Grants Officer: Denise Burgess
Performance Period: 04/01/2017-03/31/2022
Level of Funding:
Project Goal:. Nursing home (NH) health information technology (IT) is becoming more prevalent across the country. The research strategy includes a 4 round Delphi Technique with 30 NH IT experts to validate a NH IT Maturity survey that includes 29 content areas in resident care, clinical support, and administrative activities. Delphi experts will help also develop a NH IT maturity staging model based on NH IT capabilities, extent of IT use, and IT integration. Delphi expert opinion regarding the the NH IT Maturity scale and staging model will be combined to form a new survey that will be used to measure NH IT Maturity nationally, in the U.S.
Specific Aims: 1) Create a NH IT maturity survey and maturity staging model using a 4 round Delphi with NH IT experts, 2) Pilot test the NH IT Maturity Survey and staging model with NH IT experts, 3) Explore NH IT maturity using the survey and staging model during a 3-year national assessment, and 4) Examine if NH IT maturity is associated with CMS quality measures in a national sample of NHs over 3 years.
Overlap: No overlap

Title: Non-small Cell Lung Cancer (NSCLC): Data Analytics, Patient Journeys, and Patient Clusters
Time Commitment: 3.6 calendar
Supporting Agency: Roche Molecular Systems Inc.
Address: 1301 Shoreway Road, Suite 300, Belmont, CA 94002
Contracting/Grants Officer: Michael Barnes
Performance Period: 02/01/2019-01/31/2020
Level of Funding:
Project Goal: Develop interactive descriptive data dashboards to visualize patient pathways and pools linked with key clinical outcomes (e.g. cancer-specific mortality, survival), and quality and accreditation metrics.
Specific Aims: (a) Identify and define a patient cohort of aNSCLC patients dating from 2010 onward, (b) Sequentially define individual patient journeys according to laboratory diagnostic and oncology-related treatment events at cancer-related encounters, (c) and Define unique patient clusters based on key demographic and clinical data attributes necessary to identify similar patients within a given cohort.
Overlap: No overlap

Title: GPC/PCRF - PCORnet 2.0
Time Commitment: 3 calendar
Supporting Agency: Patient Centered Outcomes Research Institute (PCORI) through the University of Kansas Medical Center Research Institute

Address: 1828 L St., NW, Suite 900, Washington, DC 20036
Contracting/Grants Officer: Claudia Grossmann, PhD
Performance Period: 01/01/2019-12/31/2019
Level of Funding:
Project Goal: Provide overall network leadership for the Greater Plains Collaborative (GPC) PCORNet Clinical Data Research Network (CRN) consisting of thirteen research medical centers. This effort will evolve and support a clinical research network infrastructure that captures complete and comprehensive data from patients at thirteen medical centers. This includes developing the governance, regulatory processes, technical infrastructure, and patient engagement strategies to enable a learning health care system by integrating Comparative Effectiveness Research with clinical workflows. Develop sustainable model for this digital infrastructure.
Specific Aims: The aims include developing the governance, regulatory processes, technical infrastructure, and patient engagement strategies to enable a learning health care system by integrating Comparative Effectiveness Research with clinical workflows. Develop sustainable model for this digital infrastructure.
Overlap: No overlap

Title: DHSS Home Visiting Program/Maternal Infant and Early Childhood-Integrated Data System: REDCap v2.0
Time Commitment: 3 calendar
Supporting Agency: Missouri Department of Health & Senior Services
Address: 930 Wildwood Dr, Jefferson City, MO 65109
Contracting/Grants Officer: Venkata Garikapaty
Performance Period: 09/30/2019-09/29/2020
Level of Funding:
Project Goal: The goal of this project is to develop a data collection system for the Missouri Department of Health and Senior Services (DHSS) Maternal and Child Health Home Visiting Programs which are funded by the United States Department of Health and Human Services. The system is used by the public health workers at the local implementing agencies across the State of Missouri, which is a secure, central and completely online system.
Specific Aims: To develop and maintain an electronic data capture system using the REDCap platform.
Overlap: No overlap

Title: GPC/PCORI - PCORnet 2.0
Time Commitment: 2.4 calendar
Supporting Agency: Patient Centered Outcomes Research Institute (PCORI) through the University of Kansas Medical Center Research Institute
Address: 1828 L St., NW, Suite 900, Washington, DC 20036
Contracting/Grants Officer: Claudia Grossmann, PhD
Performance Period: 04/01/2020-09/30/2020
Level of Funding:
Project Goal: Provide overall network leadership for the Greater Plains Collaborative (GPC) PCORNet Clinical Data Research Network (CRN) consisting of thirteen research medical centers. This effort will evolve and support a clinical research network infrastructure that captures complete and comprehensive data from patients at thirteen medical centers. This includes developing the governance, regulatory processes, technical infrastructure, and patient engagement strategies to enable a learning health care system by integrating Comparative Effectiveness Research with clinical workflows. Develop sustainable model for this digital infrastructure.
Specific Aims: The aims include developing the governance, regulatory processes, technical infrastructure, and patient engagement strategies to enable a learning health care system by integrating Comparative Effectiveness Research with clinical workflows. Develop sustainable model for this digital infrastructure.
Overlap: No overlap

SUPPORT
POPESCU, MIHAIL

Current
Title: Image-Guided Biocuration of Disease Pathways From Scientific Literature
Time Commitments: 2.4 calendar
Supporting Agency: NIH/NLM, 5R01LM013392
Address:
NIH/NHLBI Information center
P.O Box 30105
Bethesda, MD 20824-0105
Contracting/Grants Officer: Alan Vanbiervliet
Performance Period: 04/01/2020 – 03/31/2024
Level of funding:
Project Goals: The goal of this study is to develop a methodology of extracting knowledge from biomedical articles' text and figures. The text knowledge will be extracted using bioBERT, deep learning NLP framework, while the figures will be processed using a convolutional network format.
Specific Aims: The specific aims are to develop an annotated dataset related to non-small cell lung cancer, to develop methodologies based on deep learning to extract pathway information from text and figures, to use a graph database (neo4j) to fuse pathway information from various articles, and investigate graph deep nets to correct and fill in missing pathway info.
Overlap: No scientific or budgetary overlap with the current proposal

Title: Washington University Center for Diabetes Translational Research
Time Commitments: 1 calendar
Supporting Agency: NIH/NHLBI, WU-17-184
Address:
NHLBI Health Information Center
P.O. Box 30105
Bethesda, MD 20824-0105
Contracting/Grants Officer:
Performance period: 07/02/2021-07/31/2026
Level of funding:
Project Goals: To develop strategies and support Diabetes translational research.
Specific Aims: The Diabetes Informatics and Big Data (DIBD) Core, a regional core located at the University of Missouri in Columbia, will advance the development of innovative approaches to study diabetes control strategies through the application of health care informatics (i.e., from clinic to community to population) and "Big Data" (BD) methods, with a particular focus on rural populations.
Overlap: No scientific or budgetary overlap with the proposed work.

Title: iCHAT-TM: Interdisciplinary Communication in Nursing Homes About Resident Transfer using Text Messages
Time Commitments: 1 calendar
Supporting Agency: NIH/NIA
Address: 1R01AG078281
Contracting/Grants Officer:
Performance period: 07/01/2022 – 6/30/2025
Level of funding:
Project Goals: Investigate the use of text messages in nursing home care.
Overlap: No scientific or budgetary overlap with the proposed work.

Title: Center to Stream Healthcare In Place (C2SHIP)
Time Commitments: 1 calendar

Supporting Agency: NSF
Address: https://www.iucrc.org/
Contracting/Grants Officer:
Performance period: 09/2022 – 09/30/2027.
Level of funding:
Project Goals: C2SHIP at MU builds on a rich history of research to help older adults and others with physical and cognitive challenges. C2SHIP leverages an academic setting that includes engineering, medicine, nursing, and other clinical disciplines located within walking distance on a single campus. Research strengths include biomedical sensing, machine learning, health informatics, and cybersecurity. This diverse team works together to develop new healthcare technologies, driven by actual clinical needs, and evaluates them in realistic settings.
Overlap: No scientific or budgetary overlap with the proposed work.

Previous

Title: SHB: Small: Computational Algorithms for Predictive Health Assessment
Time Commitments: 1 calendar (PI)
Supporting Agency: NSF/IIS
Address: NSF IIS-1115956
Contracting/Grants Officer:
Performance period: 2011-2013
Level of funding:
Project Goals: The goal of this project was to develop computational algorithms based on sensor data collected in homes. The methodology consists in predicting the possibility of early illness using supervised and unsupervised machine learning algorithms.

Title: Optimizing Display of Blood Pressure Data to Support Clinical Decision Making
Time Commitments: 1 calendar
Supporting Agency: Agency for Healthcare Research & Quality (AHRQ),
Address:
Contracting/Grants Officer:
Performance period: 07/01/15-04/30/20
Level of funding:
Project Goals: Design a new clinical interface for out-patient and in-patient blood pressure.

Title: Linguistic Summarization of Sensor Data for Early Illness
Time Commitments: 2 calendar
Supporting Agency: NIH/NLM
Address: Bethesda, MD
Contracting/Grants Officer: Alan Vanbiervliet
Performance period: 08/01/16-07/31/20
Level of funding:
Project Goals: The goal of this project was to facilitate clinical work in nursing home using sensor monitoring technology. The data collected by the monitoring sensors was transformed into text to enable easy access by the clinical personnel. Moreover, to further facilitate interpretation, the data was annotated using clinical terms extracted from the nursing notes.

Title: Multiple and Multi Sensor Research for Explosive Hazard
Time Commitments: 1 calendar
Supporting Agency: ARO/NVESD, W911NF-17-1-0183
Address:
Contracting/Grants Officer: Clare Yang
Performance period: 05/01/2017-04/30/2023

Level of funding:
Project Goals: The goal of this project is to develop image processing algorithms for object detection in infrared imagery.
Specific Aims: The specific aim is to develop deep learning algorithms for detection of explosive hazards using drone mounted infrared cameras.

Title: Supporting Rural Family Caregivers Managing Advanced Cancer Pain
Time Commitments: 1.2 calendar
Supporting Agency: NIH/NCI
Address:
Contracting/Grants Officer:
Performance period: 04/01/2020 – 03/31/2025
Level of funding:
Project Goals: The goal of this study is to develop interventions for caregivers of patients with cancer. The caregivers will be monitored using wearable sensors and the interventions will be delivered using web BCT sessions.

SUPPORT
SKUBIC, MARJORIE

Current

Title: Predicting ALS Outcomes Based on Networked Passive Sensors
Time Commitments: 0.3 months per year
Project Number: W81XWh2210491
Supporting Agency: Department of Defense
Supporting agency POC: USAMRDC Office of Research; help@eBRAP.org
Performance Period: 06/15/2022 – 06/14/2024
Level of funding:
Project Goals: The major goal of this project is to adapt the existing sensor-based alert system to facilitate early detection of physiological and functional declines among people living with ALS. We will first augment the sensor-based alert system with additional inputs from commercially available wearable sensors to capture additional important biomarkers for ALS progression (e.g.: oxygen saturation, continuous pulse). We will train and validate our existing algorithms to predict adverse health outcomes (e.g.: hospitalization, pneumonia, death) in ALS based on changes in the biomarker data. We will test three hypotheses across specific aims.
Specific aims: Aim 1: Establish feasibility and preliminary efficacy of an observational system for detecting clinical progression in people with ALS using networked home-based and wearable sensors. Aim 2: Establish a machine learning algorithm for predicting adverse health outcomes based on observed biometric data in people with ALS.
Overlap: This project

Title: Reducing COVID-19 Related Disability in Rural Community-Dwelling Older Adults Using Smart Technology
Time Commitments: 1.2 calendar months per year
Supporting Agency: NIH R01AG072935
Address: GWY BG RM 3S600, 7201 Wisconsin Ave., Bethesda, MD
Contracting/Grants Officer: Dana Plude
Performance Period: 9/1/2021 – 8/31/2024
Level of funding:
Project Goal: This project uses a smart sensor system that aims to reduce disability for rural community dwelling older adults and improve health-related quality of life, including depression and anxiety.
Specific Aims: (1) Evaluate the effect of a sensor system paired with a multidisciplinary self-management intervention as compared to the sensor system paired with standard health education care on disability and health-related quality of life after 1 year; (2) Evaluate the effect of the sensor system on secondary health outcomes (depression, anxiety, occupational performance, and caregiver burden), rates of falls, and healthcare usage; (3) Develop implementation guidance based on participant characteristics (demographics, context, resources, competencies, and preferences) to tailor and scale technology-supported self-management interventions for individuals living in rural communities.
Overlap: No scientific or budgetary overlap

Title: Using Innovative Technology to Facilitate Fall Prevention for Older Adults with Mild Cognitive Impairment
Time Commitments: 0.4 calendar per year
Supporting Agency: CDC R49CE003083 (subaward from University of Pennsylvania)
Address: CDC, Office of Grants Services, 2939 Flowers Rd. NE Mailstop TV-2 Atlanta, GA 30341
Contracting/Grants Officer: Toni Augustus-High, Grants Management Specialist Centers for Disease Control and Prevention Global Health Security Branch
Performance Period: 8/1/2021 – 7/31/2024
Level of funding: (subaward)
Project Goal: This project proposes to test an innovative approach for identifying older adults with mild cognitive impairment who are at high risk of falling.

Specific Aims: The specific aims are to: determine whether the in-home sensor system can be used to detect changes in functional mobility and gait that are more predictive of falls as compared with performance-based measures and cognitive measures; and conduct interviews with patients, families, and clinicians to assess perceptions about the intervention.
Overlap: No scientific or budgetary overlap

Title: Biomedical and Entrepreneurship Training for Aging (BETA)
Time Commitments: 0.18 months per year
Supporting Agency: NIH R25AG078150
Address: National Institute on Aging, Bethesda, MD
Contracting/Grants Officer: Yuan Luo
Performance Period: 08/15/2022 – 04/30/2027
Level of funding:
Project Goal: To develop a biomedical entrepreneurship training program to educate, train, broaden the skill set and motivate the scientific work force to promote healthy again. BETA will promote the work force towards translation of research ideas in aging, transform them as "innovative thinkers and entrepreneurial scholars," and influence their career opportunities in healthcare sectors.
Specific Aims: (1) Provide didactic training in the concepts, personnel, and processes underpinning biomedical innovation and product commercialization; (2) Complement educational programs in biomedical innovation and entrepreneurship with classroom-based and immersion experiences in scientific communication and 2) comprehensive responsible conduct of research training; (3) Provide focused immersion experiences with gerontologists, neurocognitive specialists, faculty entrepreneurs, technology transfer specialists, and small business creators; and (4) Integrate trainees' research related to aging and AD/ADRD with the BETA program by having them carry-out a team-based capstone project.
Overlap: No scientific or budgetary overlap

Title: IUCRC Phase I University of Missouri: Center to Stream Healthcare In Place (C2SHIP)
Time Commitments: 0.5 months per year
Supporting Agency: National Science Foundation CNS-2209854
Address: 2415 Eisenhower Avenue, Alexandria, VA 22314
Contracting/Grants Officer: Mohan Kumar
Performance Period: 08/15/2022 – 07/31/2026
Level of funding:
Project Goals: This Industry-University Cooperative Research Center is focused on collaborative funding by industry members, for technology projects designed to facilitate commercialization. The projects relate to technology that supports a distributed model of healthcare delivery, for example, supporting people in their homes.
Overlap: No scientific or budgetary overlap

Pending

Title: A compact and lightweight vibrotactile biofeedback device for vestibular rehabilitation
Time Commitments: 0.5 months per year
Supporting Agency: NIH/NIA
Address: National Institute on Aging, Bethesda, MD 20892
Contracting/Grants Officer: N/A
Performance Period: 4-1-2024 – 3-31-2026
Level of funding:
Project Goal: The overall objective is to develop a novel compact and lightweight head-worn vibrotactile biofeedback device and to validate its effectiveness in reducing the risk of falls for persons with vestibular dysfunction and in expediting the recovery of their vestibular system.

Specific Aims: (1) To study the real-time effectiveness of a prototype head-worn vibrotactile biofeedback device in reducing fall risk, and (2) To study the long-term effectiveness of the vibrotactile biofeedback device in facilitating the rehabilitation of vestibular function.
Overlap: No scientific or budgetary overlap

Completed

Title: Customized Health Alerts and Consumer-Centered Interfaces Using In-Home and Wearable Sensors
Time Commitments: 2.4 calendar per year
Supporting Agency: NIH R01NR016423
Address: NINR, BG 1DEM RM 727, 6701 Democracy Blvd., Bethesda, MD 20817
Contracting/Grants Officer: Kristopher J. Bough
Performance Period: 1/8/2018 – 11/30/2021
Level of Funding:
Project Goal: The project goal is to investigate new health alert algorithms that are more sensitive and more customized to the individual. We will also recruit subjects in independent living housing to solicit the views of consumers on wearable sensors, health alerts, and user interfaces that allow seniors and their family members to view the health alert information in a way that empowers them to better self-manage their own health.
Specific Aims: (1) Develop new health alert algorithms to improve the clinical relevance of the health alerts by incorporating new sensor features, multi-dimensional feature combinations, and algorithms that track trajectories in health status; (2) Customize health alerts for each older adult's needs using on-line machine learning and by integrating *user* feedback, health status and medications from an Electronic Health Record (EHR); (3) Capture consumer input on customized health alerts and user interfaces. Design a consumer interface to display information in a format that older adults and family members find easy to use and interpret, to empower them to better self-manage chronic health conditions, while addressing their privacy concerns; (4) Explore wearable sensors for older adults, including preferences, adherence, use patterns, usefulness, and the potential for automated health alerts to indicate changes in health.
Overlap: No scientific or budgetary overlap

Title: Customized Health Alerts and Consumer-Centered Interfaces for ADRD Patients and Family
Time Commitments: 0.9 calendar
Supporting Agency: NIH R01NR016423 Supplement
Address: NINR, BG 1DEM RM 727, 6701 Democracy Blvd., Bethesda, MD 20817
Contracting/Grants Officer: Kristopher J. Bough
Performance Period: 8/2/2019 – 11/30/2021
Level of Funding:
Project Goal: This project extends the parent grant with a pilot study, testing the in-home sensor system and consumer interfaces on a population of ADRD patients living in the community with family.
Specific Aims: (1) Using in-home sensors, capture sleep patterns (sleep time and quality, restlessness, sleep stages), walking gait, and general activity of ADRD patients during their normal daily activities in the home; extend the consumer interface to display these data trends; (2) Capture the user feedback of the monitored ADRD patients with neurocognitive disorder and their family members about the sensor system and consumer interface; (3) Explore changes in sensor data trends that could be used for guiding medication decisions, choosing activities that promote functionality, or tracking the effectiveness of interventions such as cognitive stimulation therapy.
Overlap: No scientific or budgetary overlap.

Title: Development and Acceptability of an Ambient In-Home Activity Assessment Tool for Stroke
Time Commitments: 0.45 calendar per year
Supporting Agency: NIH R21HD099337
Address: NICHHD, BG 6710B RM 2114, 6710B Rockledge Drive, Bethesda, MD 20817
Contracting/Grants Officer: Maria Nurminskaya
Performance Period: 9/10/2019 – 8/31/2021

Level of funding
Project Goal: This study will develop and refine an algorithm for detecting and discerning various everyday movements of individuals post-stroke in the home environment; the developed tool will also include an assessment component for stroke rehabilitation.
Specific Aims: (1) Develop the Daily Activity Recognition and Assessment System (DARAS) for activity recognition and performance assessment of people with stroke; (2) Evaluate the acceptability of the system for use in the home by people with stroke.
Overlap: No scientific or budgetary overlap

Title: REU SITE: Research in Consumer Application Networking Technologies
Time Commitments: 0.15 summer per year
Supporting Agency: NSF CNS-1950873
Address: National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314
Contracting/Grants Officer: Rebecca Shearman
Performance Period: 2/1/2020 – 1/31/2023
Level of funding:
Project Goal: This project supports a summer research experience for undergraduate students. Each year, ten undergraduates are mentored by faculty and graduate students in conducting research projects, including machine learning projects related to monitoring health-related information.
Specific Aims: Undergraduate students will investigate a variety of interesting and challenging problems that involve consumer networking applications and services that are of significance to the economy and quality of life in areas such as social computing, health care, and public safety. The students will participate in the faculty mentors' on-going funded research, investigate technically challenging issues, and develop viable solutions and insights. They will participate in professional development activities to prepare them for future graduate studies and a broad range of emerging computing careers. The site will focus on recruiting students from non-PhD granting institutions with particular emphasis on institutions in and around the state of Missouri.
Overlap: No scientific or budgetary overlap

OTHER SUPPORT

Name of Individual: Xing Song
Commons ID: XINGSONG

Current
Title of project: Towards Better Understanding of ALS using a Multi-Marker Discovery Approach from a Multi-Modal Database (ALS4M)
Project Number: R01TS000336
Effort: 15%
Performance period: 10/01/22 – 09/30/25
Supporting agency: CDC/ATSDR
Supporting agency POC: Candis Hunter (CDC/DDNID/NCIPC/OD); hlb8@cdc.gov
Project Goals: The proposed work is exploratory and developmental in nature and will be one of the first pilot studies applying machine-learning-based, hypothesis-generating algorithms on statistically powerful real-world data to generate real-world evidence on ALS risk factors with or without an existing evidence base. The work will not only provide CDC agency of toxic substance and disease registry (ATSDR) with empirical evidence to better prioritize future decisions on expanding the ALS registry risk factor survey but serve to inform better designed proposals for future etiological studies and targeted trials for ALS.
Specific Aims: Building on established well-integrated real world big data source and established ensemble embedded feature selection framework, an established multi-marker (biomarker, clinical marker, geo-marker, socio-marker) discovery algorithm will be developed to discover novel, generalizable risk factors (Aim 1); new symptomatic patterns for early diagnosis (Aim 2), and effective clinical care pathways for ALS (Aim 3).
Overlap: No overlap with current proposal

Title of project: Greater Plains Collaborative Optimizing Infrastructure for Conducting Patient-Centered Outcomes Research: PCORnet, The National Patient-Centered Clinical Research Network – Phase III
Project Number: RI-MISSOURI-01-PS1
Effort: 10%
Performance Period: 01/01/2022 – 12/31/2024
Supporting Agency: Patient Centered Outcomes Research Institute
Supporting Agency POC: Claudia Grossmann; cgrossmann@pcori.org
Project Goals: Create a research network that captures complete and comprehensive data from patients at twelve medical centers. Develop the governance, regulatory processes, technical infrastructure, and patient engagement strategies to enable a learning health care system by integrating Comparative Effectiveness Research with clinical workflows.
Specific Aims: The Greater Plains Collaborative has demonstrated our strong commitment to supporting internal and external researchers and stakeholders seeking to conduct research that is national in scope. We are enthusiastic about PCORnet's third phase and strengthening clinical effectiveness research (CER) with our patients, clinicians, researchers, and healthcare systems. GPC highlights the following strategic alignments with the Prioritizing Principles for PCORnet: 1) strengthen engagement; 2) strengthen diversity; 3) strategic alignment with national scopes; 4) build data capabilities; 5) refine shared governance and cost recovery; 6) optimize coordination and network functions; 7) advance learning health systems; 8) strengthen federal partnerships.
Overlap: This project built the PCORnet data infrastructure

Title of project: BESTMED: oBservational Evaluation of Second line Therapy MEdications in Diabetes
Project Number: S03158-01 (PCORI: DB-2020C2-20308)
Effort: 5%
Performance Period: 07/01/2021 – 06/30/2024
Supporting Agency: University of Iowa (Patient-Centered Outcomes Research Institute – PCORI flow through)
Supporting Agency POC: Emma Hegermiller; emma@bestmed.org

Project Goals: We will use a large database of electronic patient data to compare diabetes medications to determine which ones offer the best balance of risks and benefits. This database will draw from several large healthcare institutions and health insurance companies that collectively pull from a patient population of over 130 million across all major regions of the United States. We will study adults aged 30 or older who have type 2 diabetes and are at moderate (2 to 3 percent) risk of heart attacks and strokes, and who are starting a second diabetes medication (after metformin).
Specific Aims: We will use clinical trial emulation, a cutting-edge statistical technique, to compare the following classes of diabetes medications: (1) DPP4 inhibitors (alogliptin, linagliptin, sitagliptin, or saxagliptin); (2) GLP1 receptor agonists (dulaglutide, exenatide, liraglutide, or semaglutide); (3) basal insulin (degludec, detemir, glargine, or NPH); (4) SGLT2 inhibitors (canagliflozin, dapagliflozin, empagliflozin, or ertugliflozin); and (5) sulfonylureas (glimepiride, glipizide, or glyburide).
Overlap: No overlap with current proposal

Title of project: Remote Monitoring and Virtual Collaborative Care for Hypertension Control to Prevent Cognitive Decline – Phase II/GR166279
Project Number: 5R33AG068483-03
Effort: 10%
Performance Period: 08/01/2021 - 07/30/2025
Supporting agency: NIH/NIA
Supporting agency POC: Marcel Salive; marcel.salive@nih.gov
Project Goals: Pragmatic trial testing if a health-system wide approach with home blood pressure monitoring and a virtual health strategy will safely and effectively lower blood pressure and slow age-related decline in cognition while reducing cardiovascular events and risk, mortality, and health care utilization.
Specific Aims: Aim 1: Examine the vCCC's impact on the primary outcome of i) achieving goal SBP <130 mmHg and secondary outcomes of ii) cognition, iii) major adverse cardiovascular events (MACE), iii) atherosclerotic cardiovascular disease risk (ASCVD) score, iv) health care resource utilization iv) all-cause mortality and v) safety. Aim 2: Assess critical implementation outcomes relevant to system wide adoption and replicability in other health systems, including feasibility, acceptability, appropriateness, and intention to adopt the vCCC among PCPs, front-line administrators, and health system leaders.
Overlap: No overlap with current proposal

Title of project: The RECOVER Post-Acute Sequelae of SARS-CoV-2 (PASC) Electronic Health Record (EHR) Cohort Study
Project Number: EHR-02-21
Effort: 5%
Performance Period: 10/31/2021-05/23/2023
Supporting agency: Children's Hospital of Philadelphia (NIH flow through)
Supporting agency POC: Alexander Shorrock; RECOVER@chop.edu
Project goals: This is a combined retrospective and prospective, longitudinal, observational meta-cohort of individuals who will enter the cohort with and without SARS-CoV-2 infection and at varying stages before and after infection. Individuals with and without SARS-CoV2 infection and with or without PASC symptoms will be followed to identify risk factors and occurrence of PASC. This study will be conducted in the United States and subjects will be recruited through inpatient, outpatient, and community-based settings. Study data including age, demographics, social determinants of health, medical history, vaccination history, details of acute SARS-CoV-2 infection, overall health and physical function, and PASC symptom screen will be reported by subjects or collected from the electronic health record using a case report form at specified intervals. Biologic specimens will be collected at specified intervals, with some tests performed in local clinical laboratories and others performed by centralized research centers or banked in the Biospecimen Repository. Advanced clinical examinations and radiologic examinations will be performed at local study sites with cross-site standardization.
Specific aims: 1) Characterize the incidence and prevalence of sequelae of SARS-CoV-2 infection. 2) Characterize the spectrum of clinical symptoms, subclinical organ dysfunction, natural history, and distinct phenotypes identified as sequelae of SARS-CoV-2 infection. 3) Define the biological mechanisms underlying pathogenesis of the sequelae of SARS-CoV-2 infection.
Overlap: No overlap with current proposal

Title of project: Predicting ALS Outcomes Based on Networked Passive Sensors
Project Number: W81XWh2210491
Effort: 26%
Performance Period: 06/15/2022 – 06/14/2024
Supporting agency: Department of Defense
Supporting agency POC: USAMRDC Office of Research; help@eBRAP.org
Project Goals: The major goal of this project is to adapt the existing sensor-based alert system to facilitate early detection of physiological and functional declines among people living with ALS. We will first augment the sensor-based alert system with additional inputs from commercially-available wearable sensors to capture additional important biomarkers for ALS progression (e.g.: oxygen saturation, continuous pulse). We will train and validate our existing algorithms to predict adverse health outcomes (e.g.: hospitalization, pneumonia, death) in ALS based on changes in the biomarker data. We will test three hypotheses across specific aims.
Specific aims: Aim 1: Establish feasibility and preliminary efficacy of an observational system for detecting clinical progression in people with ALS using networked home-based and wearable sensors. Aim 2: Establish a machine learning algorithm for predicting adverse health outcomes based on observed biometric data in people with ALS.
Overlap: [Current Project]

Title of project: Chemotherapy Dosing in Patients with Obesity: Are Oncologists Optimally Balancing Risks and Benefits to Avoid Overtreatment and Undertreatment?
Project number: BC220896
Effort: 5%
Performance period: 07/01/2023 – 06/30/2027
Supporting agency: University of Iowa (Department of Defense flow through)
Supporting agency POC: Ashley Schneekloth; ashley.r.schneekloth.civ@health.mil
Project goals: Obese cancer patients often have other health conditions that increase the risk of serious side effects with chemotherapy and there is growing evidence that some of these drugs may be particularly toxic for these patients. However, current national guidelines state very clearly that obese cancer patients should receive the same amount of chemotherapy proportionally as those without obesity. This study will identify whether obese patients receive appropriate amounts of chemotherapy and, if not, whether the dose reductions are clinically appropriate. The project will leverage the GPC Observable Unified Study Environment (GROUSE) to collect a multi-center observational dataset based on electronic health records (EHRs) and (NAACCR) tumor registry to investigate current chemotherapy dosing strategies in patients with obesity and how it is associated with multiple health outcomes.
Specific aims: 1) Quantify the extent of non-guideline chemotherapy use for real-world patients with and without obesity. 2) Examine the clinical appropriateness and independent contribution of obesity, comorbidity, treatment-induced toxicity, organ dysfunction, and supportive care on cycle-specific chemotherapy doses. 3) Model the relationship between chemotherapy dose, toxicity, and survival to assess the real-world balance of benefits and harms of treatment in patients with and without obesity.
Overlap: this is the project under review

Title of project: Targeting KLF2 in macrophages to improve immune checkpoint therapy for hepatocellular cancer
Project Number: R01CA274949
Effort: 4%
Performance period: 04/01/2023-03/31/2028
Supporting agency: NIH
Supporting agency POC:
Project goals: To define KLF2-directed macrophages (MΦs) as the cellular basis mediating HCC pathogenesis and immune tolerance toward the development of a new therapeutic approach by integrating KLF2-KO MΦs with αPD-1 Ab and to investigate the molecular mechanism and regulators by which B.th/αPD-1 suppresses KLF2 to reprogram MΦ by controlling TLR9 and SIRPα expression.
Specific aims: We hypothesize that CpG-rich B.th reinvigorates αPD-1 Ab ICT in HCC by phenotypically and functionally programming MΦ via KLF2-controlled expression of TLR9 and SIRPα. We will test our hypothesis

through the following two aims: Aim 1. Define KLF2-directed MΦs as the cellular basis that mediates HCC pathogenesis, immune tolerance, and response to ICT-based treatments. By inducing KLF2-KO in MΦs before tumor initiation and after tumor development, we will define how KLF2-directed MΦs impact HCC tumorigenesis, immune tolerance, and response to αPD-1 Ab. Aim 2. Investigate the role of KLF2 as a master regulator that reprograms and triggers MΦ activities by controlling the expression of TLR9 and SIRPα in MΦs. We will use gain- and loss-of-function approaches to study how TLR9 and SIRPα mediate the KLF2-directed MΦ program and immune regulation in HCC growth and ICT-based therapy.
Overlap: No overlap with current project.

Title of project: Building a New Therapeutic Paradigm for Hepatocellular Cancer by Dissecting the Interaction Between Radiofrequency Ablation, Chemotherapy, and Immunotherapy
Project Number: I01BX004065
Effort: 2%
Performance period: 04/01/2023-03/31/2027
Supporting agency: USVA Medical Research Service-Merit Review
Supporting agency POC:
Project goals: To demonstrate Treg as a cellular target to improve radiofrequency ablation (RFA) on hepatocellular cancer (HCC) and enable RFA-released in situ tumor-specific antigen to activate in vivo anti-tumor immunity and to demonstrate c-Met and PD-1 as molecular targets to improve RFA on HCC and enable RFA-released in situ TSA to activate in vivo anti-tumor immunity.
Specific aims: We hypothesize that cellular blockade of Treg and molecular blockade of HGF/c-Met axis enables RFA-released in situ TSA to activate therapeutic immune toxicity and generate a synergistic therapeutic outcome. Taking advantage of the progression in developing Treg inhibitors, such as bempegaldesleukin (NKTR-214) which specifically depletes Tregs in tumor tissue but not in the periphery (16), and c-Met inhibitors, such as tivantinib, a non-adenosine triphosphate-competitive Met inhibitor, and capmatinib, a potent and selective Met kinase inhibitor, we will develop cellular and molecular therapies to test the hypothesis through our following two aims: Aim 1. Demonstrate Treg as a cellular target to improve RFA on HCC and enable RFA-released in situ TSA to activate in vivo anti-tumor immunity. Utilizing specific and therapeutically relevant techniques, we will deplete Tregs in tumors to improve RFA therapeutic efficacy for HCC and restore the capacity of RFA-released TSA to activate immune cytotoxicity. Aim 2. Demonstrate c-Met and PD-1 as molecular targets to improve RFA on HCC and enable RFA-released in situ TSA to activate in vivo anti-tumor immunity. We will investigate whether c-Met depletion in DCs will enable RFA-released in situ TSA to activate anti-tumor immunity and whether suppression of either c-Met, PD-1, or both will trigger RFA-caused immune cytotoxicity and improve therapeutic outcomes for HCC.
Overlap: No overlap with current project. Proposal recommended for funding.

Pending

Title of project: Patients with ALS Centered Outcome Research (PALSCORE) Coordinating Center
Project number: 1 OT2 NS136942-01
Effort: 30%
Performance period: 09/01/23-08/31/28
Supporting agency: NIH/NINDS
Supporting agency POC: Uchenna Obumneme Okoli; Uche.Okoli@nih.gov
Project goals: We proposed to accelerate therapeutic development and improve care delivery for people living with ALS by establishing a multidisciplinary ALS consortium with modern informatics infrastructure. The rationale is to overcome barriers to research related to the rarity of ALS, health data fragmentation into multiple databases, and the physical barriers related to ALS disease progression by reimagining a new and more effective model for collecting data and performing research in ALS by taking full advantage of existing informatic technologies, infrastructure, and established data networks such as PCORnet.
Specific aims: 1) Establish PALSCORE as a PCORnet-empowered network comprising of six interconnected cores (Administrator, Engagement, Translational and Trial, Data and Informatics, Biorepository and Biomarker, Digital and Neuroimaging) as an expansion of GPC to all PCORnet networks. 2) Assemble an ALS Data Commons (ALS-DC), at each eligible PCORnet site, expanding on the NINDS common data element (CDE)

with additional structured and unstructured data elements extracted from EHRs as well as advancing data capture capacity at point of care and patient's home (e.g., implementing ALS Toolkit). 3) Conduct a combined retrospective, cross sectional, and prospective longitudinal, natural history study leveraging PALSCORE infrastructure to generate critical real-world evidence to better understand risk factors and care models for people with ALS.
Overlap: No overlap with current project.

Title of project: Choosing IS regimens in kidney Transplant by Efficacy and Morbidity (CISTEM2)
Project number:
Effort: 20%
Performance period: 04/01/2024 – 03/31/2029
Supporting agency: NIH/NIDDK
Supporting agency POC:
Project goals: Kidney transplant (KT) care faces unprecedented challenges resulting from increased patient complexity, the need to expand acceptance of organs from non-standard donors, and challenges from broader organ sharing including longer cold ischemic times. Despite refinement in immunosuppression (IS) management over several decades, nearly all KT patients experience progressive loss of allograft function, leading to graft failure while still risking life-threatening IS-related complications. U.S. KT practice benefits from the unique availability of a national registry capturing some information on all U.S. recipients, but development of evidence-based IS management practice to optimize long term KT function has been limited by the need for detailed, longitudinal clinical data for large representative populations. Our previous NIDDK-supported R01 grant (Choosing IS regimens in kidney Transplant by Efficacy and Morbidity; CISTEM), leveraged integrated transplant registry, Medicare claims and national pharmacy clearinghouse data were used to assess the impact of initial IS regimen selection on key post-KT events: infections (pneumonia, sepsis, urinary tract infections), malignancy, new onset diabetes, as well as traditional metrics (acute rejection rate, allograft survival and patient death).1 We developed a free web-based interface to assist transplant professionals and patients in shared-decision making about IS choice at the time of KT.2 However, with IS being a lifelong requirement requiring dynamic adjustments, we seek to extend the CISTEM tools to improve long-term outcomes by applying state-of-the-art machine learning (ML) algorithms using both the CISTEM data set and a novel robust longitudinal dataset incorporating multicenter electronic medical records.
Specific aims: 1) Recognizing the lack of longitudinal and granular clinical observations and lab results, we will establish a novel CISTEM2 dataset, integrating: a) national transplant registry data granular clinical data from 12 transplant centers housed in the Greater Plains Collaborative (GPC,) a component of the Patient Centered Clinical Research Network (PCORnet); b) administrative claims; and c) social determinants of health (SDOH) indicators for KT recipients. GPC utilizes the PCORnet common data model (CMD) for all clinical data, which can be securely linked to national transplant registry, administrative claims and SDOH indicators. We will expand from the multivariable propensity and Cox proportional hazard models with time-varying covariates used in CISTEM, to more responsive and clinical meaningful endpoints such as percentage drop in KT function (via estimated glomerular filtration rate; eGFR) and the validation of computed phenotypes for key clinical events. 2) We will extend CISTEM by developing longitudinal machine learning (ML) algorithms to dynamically identify IS strategies that optimize longer-term KT eGFR, reduce cost, and limit those IS comorbidities that post-transplant patient focus groups identify as contributors to diminished quality of life. 3) We will validate the predictive models refined in Aim 1 and the ML models developed in Aim 2, using two additional PCORnet sites (12 more KT centers; Total N: 40,535 KTs). We will analyze PCORnet CDM from all centers using distributed learning models to refine the first dynamic, evidence based clinical decision tool for longitudinal IS management after KT. Balancing the risk of acute rejection, patient and graft survival, and risk of IS-related complications after KT, based on highly granular, multicenter, longitudinal clinical data from real-world patient experience, will allow patients and physicians to dynamically optimize IS in a more personalized, patient focused, and cost-effective manner.
Overlap: No overlap with current project.

Title of project: Determining Best or Inferior Drug(s) Using an Adaptive Platform for Cryptogenic Sensory Polyneuropathy (BEAT CSPN)
Project Number:
Effort: 20%
Performance Period: 11/01/2023 – 04/30/2028
Supporting agency: Patient-Centered Outcomes Research Institute
Supporting agency POC:
Project goals: A multicenter, open label, parallel group, comparative effectiveness research study comparing different treatments for Cryptogenic Sensory Polyneuropathy (CSPN). The study will use adaptive randomization (a technique that updates the treatment allocation ratio during the study based on information gained during the study) at the individual level to determine which of six study drug(s) are superior (or inferior) in reducing chronic pain among people with CSPN.
Specific aims: Aim 1: Determine which non-opioid drug is most effective in producing pain relief and improving quality of life in patients with CSPN. Aim 2: Determine which drug has the fewest and which has the most adverse side effects and determine the efficacy of each drug, combining data regarding pain reduction and quits. Aim 3: Determine efficacy and quit rate for selected non-opioid drugs for CSPN. Aim 4: Improve care of patients with CSPN by training primary care health professionals and neurologists in the diagnosis of CSPN and supporting their need to select appropriate, effective, non-opioid drugs for CSPN pain treatment.
Overlap: No overlap with current proposal

Title of project: Combination of ceramide and immunotherapy in treatment of hepatocellular cancer (renewal)
Project Number: R01CA208396
Effort: 5%
Performance period: 07/01/2023-06/30/2028
Supporting agency: NIH
Supporting agency POC:
Project Goals: To determine the cellular mechanisms by which macrophages and Tregs mediate the effect of LipC6/aCTLA4 antibody in activating anti-tumor immunity and suppressing hepatocellular cancer and to determine the molecular mechanisms by which KLF2 mediates LipC6/aCTLA4 antibody induced repression of tumor-resident Tregs and macrophages via modulating CTLA4 and Foxp3.
Specific aims: We hypothesize that LipC6/αCTLA4 Ab induces antibody-dependent MΦ phagocytosis on Treg via KLF2 signaling pathway. We will test our hypothesis through two aims: Aim 1. Determine the cellular mechanisms by which MΦ and Treg mediate the effect of LipC6/αCTLA4 Ab in activating anti-tumor immunity and suppressing HCC. We will characterize LipC6/αCTLA4 Ab-educated TAMs and Tregs, then use genetic and non-genetic approaches to investigate how MΦ and Treg depletion impact therapeutic efficacy and immune activation mediated by LipC6/αCTLA4 Ab. Aim 2. Determine the molecular mechanisms by which KLF2 mediates LipC6/αCTLA4 Ab-induced repression of tumor-resident Tregs and MΦs via modulating CTLA4 and Foxp3. We will use genetic and non-genetic approaches to induce conditional knockout (KO) of KLF2 in Tregs and MΦs, then examine the effect on LipC6/αCTLA4 Ab-primed anti-HCC immunity.
Overlap: Scored at 20 percentile.

Title of project: DRIVERs: Data systems Research to Identify driVers of Ethnic & Racial Inequities in Maternal Mortality
Project Number:
Effort: 5%
Performance Period: 11/01/2023 – 10/30/2025
Supporting agency: NIH/NINHD
Supporting agency POC:
Project goals: To better-understand hospital- and structural-level factors associated with maternal mortality and severe maternal mortality (SMM) in the US. Our central hypothesis is that social determinants of health and hospital factors significantly impact maternal and pregnancy outcomes, and are more prognostic for BIPOC (Black, Indigenous, People of Color) populations.
Specific aims: Aim 1: To elucidate the impact of structural and social determinants of health, on rates of maternal mortality and SMM, and to assess the extent to which these factors explain or predict inequity in these outcomes among Black birthing people. We hypothesize that components of structural racism such as racial residential segregation, and downstream consequences of structural racism such as neighborhood

walkability, greenspace access, employment, insurance status, and allostatic load, will have a significant association with mortality and SMM, and will help explain inequity in mortality and SMM rates between Black and White birthing people. We will utilize the Greater Plains Collaborative (PCORnet) data system to link clinical and demographic data with social security death files, obituary files, and geocoded residence data. Geocoding allows us to link structural measures via the Census and American Community Survey. We will leverage a generalized linear mixed model (GLMM) to estimate the smoothed relative risks (RRs) of mortality and SMM. Aim 2: to identify hospital-level factors associated with maternal mortality and SMM, and to assess the extent to which these factors explain or predict inequity in these outcomes among Black birthing people. We hypothesize that hospital-level factors such as medical services segregation, maternal levels of care, regions of the country, urban/rural status, and patient demographics and comorbidities have significant impact.
Overlap: No overlap with current proposal

Completed
Title of project: Predicting Outcomes in Children with Ulcerative Colitis
Project Number: 1R21DK130006
Effort: 10%
Performance Period: 07/08/2021 – 06/30/2023
Supporting agency: University of Tennessee Health Science Center (NIH flow through)
Supporting agency POC: Kaitaia Fu; fukai@niddk.nih.gov
Project Goals: The proposed project will accurately predict early and late clinical outcomes of patients following initial standard therapy in children with ulcerative colitis. The ability to develop accurate predictive models using basic clinical, endoscopic, histologic, and laboratory data would be extremely helpful to clinicians, as well as to patients/families in helping them better understand the decision-making process.
Specific aims: Aim 1: Develop unbiased predictive models with the PROTECT and Greater Plains Collaborative (GPC) data to reliably predict early and late outcomes in children with UC. Aim 2: Develop clinical decision support tool.
Overlap: No overlap with current proposal

Title of project: The Greater Plains Collaborative; a PCORnet Clinical Data Research Network – Phase II
Project number: HSRP20162183
Effort: 42%
Performance Period: 09/05/15 – 12/31/2021
Supporting Agency: Patient Centered Outcomes Research Institute
Supporting Agency POC: Claudia Grossmann; cgrossmann@pcori.org
Level of funding:
Project goals: Create a research network that captures complete and comprehensive data from patients at twelve medical centers. Develop the governance, regulatory processes, technical infrastructure, and patient engagement strategies to enable a learning health care system by integrating Comparative Effectiveness Research with clinical workflows.
Specific aims: GPC continues to highlight the following strategic alignments with the Prioritizing Principles for PCORnet: 1) strengthen engagement; 2) strengthen diversity; 3) strategic alignment with national scopes; 4) build data capabilities; 5) refine shared governance and cost recovery; 6) optimize coordination and network functions; 7) advance learning health systems; 8) strengthen federal partnerships
Overlap: No overlap with current proposal

Title of project: Remote Monitoring and Virtual Collaborative Care for Hypertension Control to Prevent Cognitive Decline (Phase I)
Project number: 1R61AG068483
Effort: 30%
Performance Period: 08/01/2021 - 07/30/2022
Supporting Agency: NIH/NIA, R61
Supporting Agency POC: Marcel Salive; marcel.salive@nih.gov
Level of funding:

Project goals: Pragmatic trial testing if a health-system wide approach with home blood pressure monitoring and a virtual health strategy will safely and effectively lower blood pressure and slow age-related decline in cognition while reducing cardiovascular events and risk, mortality, and health care utilization.
Specific aims: This study is the first phase (R61 phase) of a two-phase project testing a health-system wide approach to treating uncontrolled hypertension (HTN). The current protocol will pilot test an intervention that includes remote BP monitoring and a virtual Collaborative Care Clinic (vCCC), staffed by clinical pharmacists, to lower systolic blood pressure (SBP) to <130 mmHg, as recommended by the current American College of Cardiology/American Heart Association (ACC/AHA) guidelines.
Overlap: No overlap with current proposal

Title of project: Multilabel Statistical Modeling to Optimize Triage Decision among COVID Patients
Project number: UL1TR002366
Effort: 10%
Performance Period: 06/01/20 – 12/15/20
Supporting Agency: NIH/NCATS, Institutional Clinical and Translational Science Award
Supporting Agency POC: Mario Medina
Level of funding:
Project goals: As an important step to identify patients who would benefit the most from prolonged mechanical ventilation and to inform a better, evidence-based triage strategy, we propose to develop a robust and accurate severity scoring system specifically designed for the respiratory pandemic such as COVID-19 by exploiting an extensive features space and a variety of statistical and machine learning
Specific aims: Aim 1: Evaluate the sensitivity and specificity of SOFA-, APACHE-, SAPS-score-based metrics in predicting severity and mortality outcomes for COVID-19 patients. Aim 2: Develop and validate multiple Single-Label Learning Models (SLLMs) for outcome predictions among COVID-19 patient, based on an extensive feature space. Aim 3: Develop and validate a Multi-Label Learning Model, MLLM, to jointly predict the likelihood of ventilation duration and in-hospital mortality, which can be further decomposed into two sub-models describing the specific clinical pathways of mortality/survival with or without prolonged ventilation.
Overlap: No overlap with current proposal

Title of project: Identifying Personalized Risk of Acute Kidney Injury with Machine Learning
Project number: 1R01DK116986
Effort: 42%
Performance Period: 09/01/2019 – 12/15/2020
Supporting Agency: NIH/NIDDK
Supporting Agency POC: Ivonne Hernandez Schulman; ivonne.schulman@nih.gov
Level of funding:
Project goals: Use a novel multi-view learning technique to identify robust clinical predictors for hospitalized acute kidney injury by data mining the integrated electronic medical records. The study will also identify modifiable and causal risk factors of AKI for susceptible patient subgroups and even individual patients.
Specific aims: In Aim 1, to discover novel risk factors predictive of AKI, we propose to develop an ensemble multi-view feature selection framework to simultaneously consider the differences and interrelations between feature spaces and obtain robust knowledge by synthesizing findings from diverse patient populations across multiple institutions in nine US states. In Aim 2, to discover general modifiable causes of AKI to help physicians design more effective AKI prevention policies, we propose to develop a novel multi-cause inference method to identify causal relationships between modifiable factors and AKI for susceptible patient subgroups. In Aim 3, to explain what caused AKI in individual patients to support physicians in designing personalized AKI intervention, we propose to develop a new causal explanation method by integrating causal inference and case based reasoning to quantify patient-level causal significance of modifiable factors. The proposed study will have a significant clinical impact by not only expanding the capacity of clinicians to identify high risk patients for AKI early and advancing the general knowledge on causal and modifiable risk factors for AKI but also supporting personalized AKI intervention with suggestions on potential patient-specific actionable items. The work will not only advance AKI but also the machine learning and clinical research informatics community and the methodology developed is generalizable to other clinical domains.
Overlap: No overlap with current proposal

Title of project: Effect of ACA Medicaid Expansion on Diabetes: Diagnosis, Treatment, Patient Compliance and Health Outcomes
Project number: 5U18DP006120
Effort: 10%
Performance Period: 09/30/15 - 12/15/20
Supporting Agency: Centers for Disease Control and Prevention (CDC)
Supporting Agency POC: Bernice Moore
Level of funding:
Project goals: Study the effect of the Patient Protection and Affordable Care Act of 2010 (ACA) Medicaid expansion on diabetes diagnosis, treatment, and outcomes in adults, using data from two PCORnet clinical data research networks (CDRNs).
Specific aims: A central goal of our project is to examine how the ACA expansion of Medicaid will affect diabetes diagnosis, treatment, and outcomes among the newly enrolled. We will do so using the natural experiment that results from some states expanding Medicaid and others choosing not to do so; combined with detailed, longitudinal electronic health records (EHR) for a large population of 9 million persons in four expansion and five non-expansion states. The combination of a multi-state shock to Medicaid eligibility and large-scale access to EHR is unique. Prior studies of adult Medicaid expansions have been small-scale, short-duration, lacked detailed health records, or a combination of these limitations. The best available study, the Oregon Health Insurance Experiment, compared 6,000 new Medicaid recipients to 6,000 controls in a single state, for a two-year period. The Oregon research found large increases in diabetes diagnosis and use of diabetes medication, but no significant change in blood sugar levels. Yet any effect of Medicaid on outcomes will emerge slowly. In contrast, we estimate that we will have 100-150,000 new Medicaid recipients, 5 years of pre-treatment data to establish baseline health and match treated individuals to controls, 6 years of post-treatment data in the study period (with potential follow-up after that), and several treated state, with different Medicaid programs, and potential to expand to additional states. This will let us study both near- and medium term outcomes, and assess whether treatment effects vary with personal characteristics or the nature of the Medicaid program. A second project goal is to innovate in causal inference methods. We will combine difference-in-differences (DiD), matching, and multiple imputation methods. We will use matching and multiple imputation methods to match control persons in non-expansion states, to match to new Medicaid enrollees in expansion states. We will use distributed lag regressions to map the emergence of any treatment effect over time. DiD, matching, and multiple imputation methods have not to our knowledge been combined in a single study. This combined design will be useful in studying other health insurance expansions.
Overlap: No overlap with current proposal

Title of project: Association Between Weight Change and Cardiometabolic Risk Factors in a Real-World Population of U.S. Adults Novo Obesity
Project number:
Effort: 10%
Performance Period: 07/17/2019 - 07/16/2020
Supporting Agency: Duke University / Duke Clinical Research
Supporting Agency POC: Susan Hayden
Level of funding:
Project goals: Given the significant population health impact of obesity, this project will leverage electronic health record (EHR) data from a network of sites to examine the current landscape of obesity and the relationship between weight change and cardiometabolic risk factors in a real-world population in the United States.
Specific aims:
Overlap: No overlap with current proposal

Title of project: Sepsis Predictive Risk Modeling Learned from Information Security
Project number:
Effort: 10%
Performance Period: 08/01/17 – 07/31/18
Supporting Agency: KCALSI, Kansas City Area Life Sciences Institute

Supporting Agency POC: Keith Gary,
Contracting/Grants Officer:
Level of funding:
Project goals: Develop predictive models for patients with sepsis, assessing what clinical factors would make physicians move faster in treating patients with suspected sepsis.
Specific aims:
Overlap: No overlap with current proposal