

AWARD NUMBER: W81XWH-17-1-0477

TITLE: Validating Community-Based Measures of Activity in Ambulatory Duchenne Muscular Dystrophy

PRINCIPAL INVESTIGATOR: McDonald, Craig M.

CONTRACTING ORGANIZATION: University of California Davis
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14. ABSTRACT This research project will validate use of patient generated step and activity data for data collection at the point-of-care to support use of stride rate patterns as an outcome measure for ambulatory patients with DMD. We will include step activity monitoring by laboratory and consumer level step monitoring devices that can feed data through Apple HealthKit into the UC Davis instance of the Epic electronic medical record system. Up to 60 ambulatory patients with DMD will be recruited to represent the early, middle and late stages of the progressive loss of ambulation in DMD. Up to 150 control patients will be recruited and split into similar age ranges. Participants will be assessed using step monitoring devices and traditionally performed clinical outcome measures, followed by community monitoring. StepWatch™ data collected from two previously enrolled cohorts of children with DMD will also be used for longitudinal analyses and determination of responsiveness to steroid treatment.					
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1. INTRODUCTION: Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

Background: Development of novel technologies and therapeutic agents to treat Duchenne muscular dystrophy (DMD) have increased interest by regulatory bodies such as the Food and Drug Administration in the development of “clinically-meaningful” study endpoints for clinical trials. There is a need for the development of valid measures of ambulatory ability in very young children while effectively evaluating treatment effects in clinical trials.

Objective: This proposal focuses on validating the use of patient generated step and activity data to facilitate future data collection at the point-of-care to support the development of stride rate patterns as an outcome measure for ambulatory patients with DMD. It is to include step activity monitoring by StepWatch™ and a consumer level step monitoring devices (Garmin VivoActiveHR and Polar M400 activity watches and the Polar StrideSensor activity monitor) that can feed data through Apple HealthKit into the UC Davis instance of the Epic electronic medical record system. Up to 60 ambulatory patients with DMD will be recruited to represent the early, middle and late stages of the progressive loss of ambulation in DMD. Patients will be sorted into three age groups of (n=20) participants: early (ages 2-6), middle (ages 7-11) and late (ages 12-16). Up to 150 control participants will be recruited and split into similar age ranges. Participants will be assessed using step monitoring devices and traditionally performed clinical outcome measures (6MWT, TFTs, NSAA), followed by community monitoring. StepWatch™ data collected from two previously enrolled cohorts of children with DMD will also be used for longitudinal analyses and determination of responsiveness to steroid treatment. We will develop model plans for data collection, validation, visualization, transfer, archival and lock of raw instrument data, as well as guidelines for integration with existing data platforms including EPIC electronic health records and I2B2 NIH data repository.

Applicability: Well-designed community mobility measures can be used in both clinical trials and day-to-day clinical practice. For clinical trials, they provide researchers with the ability to measure day-to-day walking ability across a broad range of ages, including very young children with DMD. Those results can then also be compared to other clinical trial measures such functional evaluations and timed function tests to help teach researchers and regulatory authorities about how “in clinic” tests commonly used in clinical trials relate to a persons’ mobility in their daily life and whether those tests are “clinically meaningful”. Within 3 years, this project will be able to produce such a tool.

Impact and Contributions: Data from this project will provide the basis for development of a “clinical trialready” community mobility measure that has been constructed against a background of comprehensive clinical assessments of functional ability across the range of ambulatory ability. This measure will be rapidly usable as a sensitive measure for use in the growing field of DMD clinical trials, and will help to demonstrate “clinically meaningful” results to regulatory agencies in charge of new drug approval.

2. KEYWORDS: Provide a brief list of keywords (limit to 20 words).

Duchenne muscular dystrophy
Community Mobility
mHealth
Patient Generated Health Data
Accelerometers
Clinical Trial Outcomes Development
DMD Natural History

- 3. ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Aim 1: Comparison of accuracy and validity of both laboratory- and consumer-grade step activity monitoring devices, and comparison to traditional clinical evaluator determined laboratory-based measures.

- Aim 1.1: Evaluate validity and correlation of stride activity data using laboratory and consumer grade devices.
- Aim 1.2: Determine concurrent validity of stride rate patterns by accelerometry as compared to the 6-minute walk test, North Star Ambulatory Assessment and Timed Motor Performance Tests in DMD patients who are able to perform these assessments.

Aim 2: Evaluation of age-related patterns in community step monitoring data in DMD and typically developing youth controls.

- Aim 2.1 Evaluate differences between DMD and TDY in overall daily patterns of activity by age group across all levels of stride rate activity.
- Aim 2.2 Evaluate differences between DMD and TDY for area under the curve for total time and height-adjusted distance overall and at each stride rate and stride activity level group.
- Aim 2.3 Evaluate Differences between age groups that represent disease progression in DMD for area under the curve for total time and height-adjusted distance overall and at each stride rate and stride activity level group.

Aim 3: Evaluation of historical community stride monitoring data from natural history studies and clinical trials to evaluate longitudinal change and steroid response characteristics.

- Aim 3.1 Evaluate longitudinal rate of change characteristics of stride activity monitoring in DMD using historical natural history data.
- Aim 3.2 Evaluate longitudinal rate of change characteristics of stride activity monitoring to identify differences due to glucocorticoid therapy using historical clinical trial data.

Aim 4: We will develop, evaluate and provide recommendations for a framework to collect, and track patient generated health data in the electronic health record for clinical care and to transfer this data into a database to meet Federal 21CFR11 compliance for clinical research.

- **Aim 4.1:** Develop guidelines for developing a platform to collect PGHD, guidelines for storage, visualization and providing clinical care in the EPIC electronic health record.
- **Aim 4.2:** Provide guidelines for the transfer of de-identified patient-generated health data (PGHD) collected via this methodology to meet FDA 21CFR11 compliance. In addition develop guidelines for sharing deidentified PGHD using a platform like the I2B2 NIH data repository for clinical research.

What was accomplished under these goals?

Phase I Activities: Study Preparation and Initiation

Quarter 1: Submitted revised scope of work and timeline with 1-year no-cost extension anticipated.

Task 1 – Human Subject Protection Approval Submission to DoD (Months 1-3): The project PI and co-investigators will develop a human subjects protocol and consent documentation for clinical evaluations and will obtain IRB approval from UC. Institutional IRB approvals will be submitted to DoD HRPO for revision and approval. DoD revisions will be reviewed and approved by the Institutional IRB. This task will be completed by Drs. McDonald and Henricson and Mr. Owens.

- UCD IRB Submitted Q1
- UCD IRB approval Q2 and submitted to HRPO
- HRPO review pending Q3
- HRPO review received (end of Q4) minor changes now pending with UCD

Task 2 – Equipment Procurement and Distribution (Months 1-3): The project coordinator will obtain stride rate monitor systems and other materials required to conduct study evaluations. This task will be completed by Ms. Nicorici and Mr. Branum. **COMPLETE**

Task 3 – Clinical evaluator methodological training for clinical assessments (Month 3): The project investigators and clinical evaluators will meet centrally to harmonize evaluation techniques. This task will be completed by Dr. McDonald, Dr. Henricson, and Ms. Nicorici. **COMPLETE**

Task 4 – RedCap database and electronic data capture system design (Months 2-3): The project data manager will construct a study database and online web-accessible electronic case report form system to ensure accuracy and completeness of data entry. All study evaluation data will be captured using paper-and-pencil clinic worksheets and will be transcribed into electronic forms by study clinical evaluators and study coordinators. Raw data from stride rate monitors will be uploaded and archived as individual files and will be associated with specific participants and visits to facilitate later compilation and analysis. RedCap enables data monitoring and editing features that are compliant with FDA requirements for electronic recordkeeping in clinical trials. The RedCap system is provided free of charge for UC-associated studies via the UC Davis Clinical and Translational Science Center. Additional technical details are available at <http://www.ucdmc.ucdavis.edu/ctsc/redcap/>. This task will be completed by Mr. Owens. **COMPLETE**

Phase III Activities: Retrospective Data Analysis and Publications

Task 1-2 – Data analysis and development of publications (Year 3-4): Data analysis will be conducted for Aim 3 activities per the study data analysis plan. Investigators will draft manuscripts for publication in a reputable peer-reviewed journal. This task will be completed by Drs. McDonald and Henricson and the study team. **Complete data to be received by end of October, 2019.**

What opportunities for training and professional development has the project provided?

Nothing to Report

How were the results disseminated to communities of interest?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?

Nothing to Report

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 principal 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?

Nothing to Report

What was the impact on society beyond science and technology?

Nothing to Report

5. **CHANGES/PROBLEMS:** The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official 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

Nothing to Report

Actual or anticipated problems or delays and actions or plans to resolve them

We experienced significant delays in project implementation due to movement of our Davis campus laboratory, which involved demolition of our old space and construction and configuration of the new space, which is now complete and operational as of June, 2019. The Sacramento campus lab is being moved during the summer of 2019, but we do not anticipate significant impact to operations or resources. In conjunction with the lab move, we also experienced loss of our project manager and key mobile health technician Corey Owens who moved to a different position within the University’s Center for Health and Technology, and one of the mobile health technicians working with Dr. Dhamar, our co-investigator from the UC Davis mobile health (mHealth) group. To remedy these challenges, we have made the following arrangements:

- Laboratory testing space has been relocated in Davis to the new UC Davis Human Performance Laboratory in Hickey Gymnasium.
- We have brought the project under the direct management of the UC Davis Neuromuscular Research Center clinical research team, which includes the center’s Clinical Research Manager Erica Goude and regulatory clinical research coordinator Omaid Sarwary. Ms. Goude and Mr. Sarwari will oversee day to day aspects of participant recruiting, visit scheduling and data collection for the study, and together they will replace the study management functions previously held by Mr. Owens.
- We have posted an appointment for an academic technical position (UC Davis Junior Specialist) to support day to day mobile health technical aspects of the project, with hiring anticipated in July of 2019.

At present, we have obtained UC Davis IRB approval for the project and we have completed activities related to the logistical setup of data collection and storage systems. We are awaiting final HRPO approval. Dr. Dhamar is working with technical specialists from the mHealth group to set up data capture and transfer protocols necessary to collect community data using the wearable sensor systems employed in the project. We have adjusted the project timelines below to account for delays, and we anticipate that we will request a 1-year no-cost extension following Year 3 to compensate for challenges experienced to date. The 1-year extension will be sufficient to adequately complete the project.

Changes that had a significant impact on expenditures

PROJECT staffing-related challenges noted in the quarterly reports and delays in HRPO approval have resulted in a temporary hold on project expenditures for staff and materials. With HRPO approval and commencement of participant enrollment, study operations will resume according to the revised Statement of Work.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to Report

Significant changes in use or care of human subjects

Nothing to Report

Significant changes in use or care of vertebrate animals

Nothing to Report

Significant changes in use of biohazards and/or select agents

Nothing to Report

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

Nothing to Report

Journal publications

Nothing to Report

Books or other non-periodical, one-time publications.

Nothing to Report

Other publications, conference papers and presentations.

Nothing to Report

Website(s) or other Internet site(s)

Nothing to report

- **Technologies or techniques**

Nothing to Report

- **Inventions, patent applications, and/or licenses**

Nothing to Report

- **Other Products**

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

- Name: Craig McDonald, MD (PI) - No Change
- Name: Erik Henricson, MPH (Co-Investigator) - No Change
- Name: Madan Dharmar, PhD (Co-Investigator) - No Change
- Name: Alina Nicorici, BS (Clinical Evaluator) - No Change

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Mr. Corey Owens left our research group. Per our revised SOW, study management tasks have been assumed by staff of our Neuromuscular Research Center's clinical trials group.

What other organizations were involved as partners?

Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.

QUAD CHARTS: If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.

- 9. APPENDICES:** Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

- 1. Revised SOW (Previously Submitted)**

APPENDIX 1: Statement of Work (Revision 1)

Summary of Revisions

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Objectives and Specific Aims

This proposal focuses on validating the use of patient generated step and activity data to facilitate future data collection at the point-of-care to support the development of stride rate patterns as an outcome measure for ambulatory patients with DMD. It is to include step activity monitoring by StepWatch™ and a consumer level step monitoring devices (Garmin VivoActiveHR and Polar M400 activity watches and the Polar StrideSensor activity monitor) that can feed data through Apple HealthKit into the UC Davis instance of the Epic electronic medical record system. Up to 60 ambulatory patients with DMD will be recruited to represent the early, middle and late stages of the progressive loss of ambulation in DMD. Patients will be sorted into three age groups of (n=20) participants: early (ages 2-6), middle (ages 7-11) and late (ages 12-16). Up to 150 control patients will be recruited and split into similar age ranges. Participants will be assessed using step monitoring devices and traditionally performed clinical outcome measures (6MWT, TFTs, NSAA), followed by community monitoring. StepWatch™ data collected from two previously enrolled cohorts of children with DMD will also be used for longitudinal analyses and determination of responsiveness to steroid treatment. We will address the following specific aims:

Aim 1: Comparison of accuracy and validity of both laboratory- and consumer-grade step activity monitoring devices, and comparison to traditional clinical evaluator determined laboratory-based measures.

Aim 1.1: Evaluate validity and correlation of stride activity data using laboratory and consumer grade devices.

Aim 1.2: Determine concurrent validity of stride rate patterns by accelerometry as compared to the 6-minute walk test, North Star Ambulatory Assessment and Timed Motor Performance Tests in DMD patients who are able to perform these assessments.

Aim 2: Evaluation of age-related patterns in community step monitoring data in DMD and typically developing youth controls.

Aim 2.1 Evaluate differences between DMD and TDY in overall daily patterns of activity by age group across all levels of stride rate activity.

Aim 2.2 Evaluate differences between DMD and TDY for area under the curve for total time and height-adjusted distance overall and at each stride rate and stride activity level group.

Aim 2.3 Evaluate Differences between age groups that represent disease progression in DMD for area under the curve for total time and height-adjusted distance overall and at each stride rate and stride activity level group.

Aim 3: Evaluation of historical community stride monitoring data from natural history studies and clinical trials to evaluate longitudinal change and steroid response characteristics.

Aim 3.1 Evaluate longitudinal rate of change characteristics of stride activity monitoring in DMD using historical natural history data.

Aim 3.2 Evaluate longitudinal rate of change characteristics of stride activity monitoring to identify differences due to glucocorticoid therapy using historical clinical trial data.

Aim 4: We will develop, evaluate and provide recommendations for a framework to collect, and track patient generated health data in the electronic health record for clinical care and to transfer this data into a database to meet Federal 21CFR11 compliance for clinical research.

Aim 4.1: Develop guidelines for developing a platform to collect PGHD, guidelines for storage, visualization and providing clinical care in the EPIC electronic health record.

Aim 4.2: Provide guidelines for the transfer of de-identified patient-generated health data (PGHD) collected via this methodology to meet FDA 21CFR11 compliance. In addition develop guidelines for sharing de-identified PGHD using a platform like the I2B2 NIH data repository for clinical research.

Project Timeline (REVISED)

Study-specific tasks and activities are displayed in the table below.

Project/Task	Year 1			Year 2				Year 3				Year 4				
	1	2	3	1	2	3	4	4	1	2	3	4	1	2	3	4
Phase I: Study Preparatory and Initiation Activities																
Develop Study Protocol and obtain IRB approvals (Institutional and DoD)	C															
Equipment Procurement and Distribution	C															
Site evaluator methodological training for functional assessments	C															
Database and electronic data capture system setup	C															
Annual IRB Review					C				X				X			
Study Recruiting, Advertising and Outreach via clinic networks, advocacy organizations, patient registries and social media outlets.		X	X	X	X	X	X	X	X	X	X	X	X	X		
Phase II: Clinical Study Conduct (Aims 1 and 2)																
Recruit and collect data on 60 DMD children and 150 controls (age 2-16 years).		X	X	X	X	X	X	X	X	X	X	X	X	X		
Electronic data capture, data monitoring and cleaning.		X	X	X	X	X	X	X	X	X	X	X	X	X		
Database lock									X				X			
Analyze data. Write up paper regarding Aim 1.1 on reliability and validity data.									X	X	X		X	X	X	
Analyze data. Write up paper regarding Aim 1.2 on comparisons with community and clinical measures.									X	X	X		X	X	X	
Analyze data. Write up paper regarding Aim 2.1 and 2.2 on comparison of activity patterns in DMD vs controls.										X	X	X		X	X	X
Analyze data. Write up paper regarding Aim 2.3 on comparison of activity patterns with DMD progression										X	X	X		X	X	X
Phase III: Retrospective Data Analysis and Publications (Aim 3)																
Analyze data. Write up paper regarding Aim 2.1 on 1-year longitudinal change using McDonald Shriners' Hospital consortium data.		X	X	X					X	X	X	X	X	X	X	X
Analyze data. Write up paper regarding Aim 2.2 on magnitude of glucocorticoid effect using PTC Therapeutics clinical trial group data.					X	X	X		X	X	X	X	X	X	X	X
Phase IV: Development of data integration platform guidelines (Aim 4)																

Develop guidelines for electronic data transfer and storage platform construct for community-derived mobile health data for medical records.	×	×	×	×						X	X	X	X	X	X	X	X
Develop guidelines for 21 CFR 11-compliant electronic data transfer and storage platform construct for community-derived mobile health data for research.				×	×	×	×			X	X	X	X	X	X	X	X
Simulate and test community step data transfer process from consumer device through EPIC EMR and research databases.							×	×		X	X	X	X	X	X	X	X
Write up paper regarding Aim 4 platform guidelines and recommendations.										X	X	X	X	X	X	X	X

Detailed Activities by Grant Phase

Phase I Activities: Study Preparation and Initiation

Task 1 – Human Subject Protection Approval Submission to DoD (Months 1-3): The project PI and co-investigators will develop a human subjects protocol and consent documentation for clinical evaluations and will obtain IRB approval from UC. Institutional IRB approvals will be submitted to DoD HRPO for revision and approval. DoD revisions will be reviewed and approved by the Institutional IRB. This task will be completed by Drs. McDonald and Henricson and Mr. Owens.

- UCD IRB Submitted Q1
- UCD IRB approval Q2 and submitted to HRPO
- HRPO review pending Q3
- HRPO review received (end of Q4) minor changes now pending with UCD

Task 2 – Equipment Procurement and Distribution (Months 1-3): The project coordinator will obtain stride rate monitor systems and other materials required to conduct study evaluations. This task will be completed by Ms. Nicorici and Mr. Branum. **COMPLETE**

Task 3 – Clinical evaluator methodological training for clinical assessments (Month 3): The project investigators and clinical evaluators will meet centrally to harmonize evaluation techniques. This task will be completed by Dr. McDonald, Dr. Henricson, and Ms. Nicorici. **COMPLETE**

Task 4 – RedCap database and electronic data capture system design (Months 2-3): The project data manager will construct a study database and online web-accessible electronic case report form system to ensure accuracy and completeness of data entry. All study evaluation data will be captured using paper-and-pencil clinic worksheets and will be transcribed into electronic forms by study clinical evaluators and study coordinators. Raw data from stride rate monitors will be uploaded and archived as individual files and will be associated with specific participants and visits to facilitate later compilation and analysis. RedCap enables data monitoring and editing features that are compliant with FDA requirements for electronic recordkeeping in clinical trials. The RedCap system is provided free of charge for UC-associated studies via the UC Davis Clinical and Translational Science Center. Additional technical details are available at <http://www.ucdmc.ucdavis.edu/ctsc/redcap/>. This task will be completed by Mr. Owens. **COMPLETE**

Task 5 – Annual IRB Review (Years 2&3, Month 1 *approximately*): Annual human subject protection review activities will be conducted as required by institution IRB and DoD committees. This task will be completed by Drs. McDonald and Henricson and Mr. Sarwari. **COMPLETE**

Task 6- Study Recruiting, Advertising and Outreach via clinic networks, advocacy organizations, patient registries and social media outlets (Year 3, Month 6 – Year 4, Month 6): Following IRB approval of outreach and recruitment documentation, the UC Davis Neuromuscular Center outreach coordinator will distribute study announcements via UC Davis Neuromuscular Research Center, Muscular Dystrophy Association clinics and surrounding regional referral centers, participants in the UC Davis Neuromuscular Disease Research Registry (<http://www.ucdmc.ucdavis.edu/pmr/research/Registry.html>), the UC Davis Neuromuscular Research Center Facebook page (<https://www.facebook.com/UCDavisPMR>), the Muscular Dystrophy Association Clinical Research Network and the Parent Project Muscular Dystrophy DuchenneConnect Registry. This task will be completed by Ms. Goude and Ms. Nicorici. **Beginning October 2019**

Phase II Activities: Clinical Study Conduct

Task 1 - Recruit and collect data on 60 DMD and 150 typically-developing children (2-16 years) (Year 3, Month 6 – Year 4, Month 6): Participants will be evaluated per the study evaluation protocol at UC. This task will be completed by Ms. Goude, Ms Nicorici, the project specialist (TBD) and Drs. McDonald and Henricson. **BEGINNING 3rd QUARTER 2019**

Task 2 - RedCap electronic data capture (Year 3, Month 6 – Year 4, Month 6): Data from clinical evaluations will be entered into the electronic case report form system. This task will be completed by clinical study team. **BEGINNING 3rd QUARTER 2019**

Task 3 – Database lock (Year 4, Month 6): To facilitate timely data analysis for Aim 1 and 2 activities, data queries will be finalized and data will be “locked” from further changes. A analysis-ready data file for use in either SAS, Systat or Stata will be extracted from the electronic data capture system using native functions and will be distributed to the investigator team involved in data analysis. Stride monitor files for each included participant visit will be compiled and provided in similar fashion to the investigator team. This task will be completed by Dr. Dharmar.

Task 4-7 – Data analysis and development of publications (Year 4): Data analysis will be conducted for Aim 1 and Aim 2 activities per the study data analysis plan. Investigators will draft manuscripts for publication in a reputable peer-reviewed journal. This task will be completed by Drs. McDonald and Henricson and the study team.

Phase III Activities: Retrospective Data Analysis and Publications

Task 1-2 – Data analysis and development of publications (Year 3-4): Data analysis will be conducted for Aim 3 activities per the study data analysis plan. Investigators will draft manuscripts for publication in a reputable peer-reviewed journal. This task will be completed by Drs. McDonald and Henricson and the study team. **Complete data to be received by end of October, 2019.**

Phase IV Activities: Development of Data Integration Platform Guidelines

Task 1 - Develop guidelines for electronic data transfer and storage platform construct for community-derived mobile health data for medical records (Year 3-4). As stated in Aim 4.1 activities, investigators will develop guidelines for developing a platform to collect PGHD, guidelines for storage, visualization and providing clinical care in the EPIC electronic health record. This task will be completed by Dr. Dharmar, with input from Drs. McDonald and Henricson.

Task 2 - Provide guidelines for the transfer of de-identified patient-generated health data (PGHD) to meet FDA 21CFR11 compliance (Year 3-4). As stated in Aim 4.2 activities, investigators will develop guidelines for 21 CFR 11-compliant electronic data transfer and storage platform construct for community-derived mobile health data for research. In addition they will develop guidelines for sharing de-identified PGHD using a platform like the I2B2 NIH data repository for clinical research. This task will be completed by Dr. Dharmar, with input from Drs. McDonald and Henricson.

Task 3 – Develop a guidance document and manuscript reflecting system design recommendations and implementation (Year 3-4). Investigators will draft a manuscript for publication in a reputable peer-reviewed journal. This task will be completed by Dr. Dharmar, with input from Drs. McDonald and Henricson.