Business Case for Assistive Technology Solutions for Parkinson's Disease

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Executive Summary

CamNtech is a private company limited by shares. The core business is the manufacturing of irradiation, electromedical and electrotherapeutic equipment. This company has $1,280,000 on hand cash, total assets of $427,350,00 and $2,353,000 in working capital. Committed to improving the lives of those with PD with advanced medical technologies, methodologies created by CamNtech LTD and delivered through a low price, value propositions, maximum automation, and extensive outsourcing, the promotion of generated knowledge, and the commercialization of their research and development (R & D) demonstrate continuing commitment to patient safety and product quality. Providing objective outcome measures for research, clinical applications, and practical interventions with demonstrated efficacy in enhancing patient adherence, CamNtech's MotionWatch8 is the next generation of tri-axial accelerometers for automated recording of event-related potentials during passive cognitive tasks in patients with Parkinson's.

The report's scope extends from implementation, initiation, planning, executions, closure, and management. It then is back up by the Parkinson's Scientific Advisory Board, FDA compliance of the Investigational New Drug/Investigational Device Exemption (IND/IDE) Taskforce of the Clinical and Translational Science Award (CTSA), clinical assessments, site feasibility, data architecture, ongoing oversight, and site visits. The study points out how wearable technologies will be a milestone in Activities of Daily Living for Parkinson's patients and businesses.

Introduction

Affecting 7-10 million people worldwide, according to Dorszewska et al. (2016), Parkinson's Disease (PD) is an age-related, progressive degeneration of specific brain areas. It is the second most common neurodegenerative disorder after Alzheimer's (Baekelandt et al., 2015). It is characterized by essential tremor (ET) when muscles are at rest (Nisticò, 2011), muscle rigidity, slowness of voluntary movements, and postural instability to secondary tasks of balance disturbance and instability (Morris, 2000). In many people, thinking becomes impaired, or dementia develops, leaving the patient incapable of self-care. These devastating effects on patients and the long-term clinical course impose a personal and economic burden on families, caregivers, and society. Currently, there is no cure for the disease, and the causation remains unknown.

CamNtech (Byrom et al., 2018) uses specialized software and MotionWatch devices to detect Periodic Limb Movement in Sleep (PLMS), which can either be symptoms of Parkinson's Disease or disorders of the central nervous system. The software will present an objective function for the management and redefine the research criteria for diagnosing this complex disease by considering clinical features, pathological findings, genetics, or molecular mechanisms. In the Systematic Review; January 2006 – December 2016 conducted by IEEE Xplore, Science Direct, and PubMed of How Wearable Sensors Can Support Parkinson's Disease Diagnosis, and Treatment Central (Rovini et al., 2017), successful implementation of this project will help demonstrate the usefulness of wearable devices for PD applications to identify early diagnosis, tremor, body motion analysis, motor fluctuations (On-Off phases), and home and long-term monitoring.

Needs/Problems

The miniaturization, sophistication, proliferation, and accessibility of technologies enable capturing more previously inaccessible phenomena in Parkinson's. However, more information has not translated into a greater understanding of disease complexity to satisfy diagnostic and therapeutic needs. This project's success will hinge on delivering a reliable, scalable measurement and analysis system that would help inform clinical programs across critical areas of PD diagnosis and treatment within the healthcare system.

Goals/Objectives

Not all activity-related disease symptoms can be accurately captured in assessing the severity of symptoms in patients with PD. Used in research, actigraphy is a well-established method for monitoring sleep quality, and circadian stability, examining activity level over time, and whether a change in activity was associated with disease severity. The aim is to improve clinical trials governed under subjective or objective configurations and use existing procedures to transfer accurate data efficiently.

Test scenario 1 referred to the ability to move from one place to another. Parkinsonian Gait or Freezing of Gait (FoG) (Mancini et al., 2019) is an abnormal gait pattern in which temporary sequences of an inability to stop or turn despite the intention to walk increase the risk of falling. According to Pickering et al. (2007), compared to straight walking, studies have shown that the risk of falling is higher and can lead to progressive episodes of FoG during turning.

Test Scenario 1 indicated that turns could have different lengths, angles, and support bases. Although results show that as the total duration of a turn increases, the stride length and velocity decrease, and more strides are needed to complete a PD population turn, one can assume

that long-term monitoring of patients during a day can provide better insight into their disease condition than time-limited examinations inside the clinics.

Test Scenario 2 involved The Internet of Things (IoT), a global ecosystem of information and communication technologies aimed at connecting any object (thing) at any time and place to each other and the Internet. According to Balas et al. (2019, p. 246), analyzing the security of Wearable Internet-of-Things (WIoT) devices is considered a complex task due to their heterogeneous nature. There is an urgent need to develop advanced mechanisms that, on the one hand, can determine if a wearable device complies with a set of predefined security requirements and, on the other hand, can decide if malicious applications compromise the device.

Test scenario 2 generated arbitrary real-time simulations for all anomalies during the test and a correlation between these anomalies to identify and detect the context-based attacks executed in the testbed. Results indicated inadequate key data management at rest and in motion could lead to reputation damage, the Department of Justice investigation, civil and criminal penalties for HIPAA violations, and the organization's long-term stability. Central to factors that dictate the value of any application to its users, there is no need for the application.

Procedures/Scope of Work

Two strategies were identified hands-on patient training at the time of purchase and a classroom troubleshooting class for the engineering department. As many PD patients struggle with the diagnosis and treatment of the motor functions caused by the disease, drug therapy, self-care, instructions, and follow-up plans, the hands-on patient training toolkit was designed to help clinicians take a systematic approach to reduce the complexity of caregiving and ensure that patients can succeed in the health care environment. To obtain optimal health outcomes, patients need health care access, health knowledge, and behavior change. To help patients and clinicians

accomplish these goals, we have identified four change areas that are important for promoting health literacy in your practice to include:

- Improve Spoken Communication - Increased pressures on primary care physicians limit the time they can spend with patients, causing many to rush through multiple points during the encounter. These factors lend to the problem of misunderstanding and poor retention of information
- Improve Written Communication - The inability to read and comprehend such things can prevent clinicians from obtaining an accurate medical history. It can also impact the patient's ability to understand medical advice, take medication correctly and safely, engage in self-care behaviors, and make informed decisions about their health care
- Improve Self-Management and Empowerment - An essential part of patient-centered medical care is enabling patients to share responsibility for their health. Ultimately, it is the patients who have to adopt a healthy lifestyle and manage their chronic condition
- Improve Supportive Systems - Patients face many barriers to achieving optimal health outcomes, many of which cannot be overcome within the walls of a primary care office. Clinicians can link patients to community organizations and government agencies to assist patients with obtaining insurance coverage, medication assistance, case management, mental health services, primary adult education, and support services for specific health needs

Timetable

	Description of Work	Activities	Responsibility	Start and End Dates
Phase One	Initiation • Business Case • Feasibility Study • Terms of Reference	Approve mission need	Resource Broker/Project Manager/Board of Directors	Monday, April 5, 2021 – Friday, July 9, 2021
Phase Two	Planning • Project Plan • Resource Plan • Financial Plan • Quality Plan • Acceptance Plan	Approve alternative selection and cost range	Resource Broker/Project Manager	Wednesday, May 5, 2021 – Thursday, September 9, 2021
Phase Three	Execution • Change Process • Change Form • Change Register • Risk Process • Risk Form • Risk Register	Approve performance baseline and start of the project	Resource Broker/Project Manager/Board of Directors/Scientific Advisory Board/ Engineers	Thursday, September 2, 2021 – Thursday, November 30, 2023

Budget (CamNtech, 2015)

	Description of Work		Start and End Dates
Phase One	Investors: Five Funding Rounds	**$350,000,000**	Monday, April 5, 2021 – Friday, July 9, 2021
Phase Two	Physical Location	**$12,800,000**	Wednesday, May 5, 2021 – Thursday, September 9, 2021
Phase Three	Marketing: Augmented Platform Opportunities	**$250,000**	Thursday, September 2, 2021 – Thursday, November 30, 2023
Phase Four	Organizational: FDA Clearance	**$62,000,000**	Thursday, September 16 – Wednesday, March 2, 2022
Phase Five	Technology Components: Operators, network administrators, and system specialist	**$2,300,000**	Thursday, September 30, 2021 – Wednesday, March 2, 2022
Total		**$427,350,000**	

Key Personnel

Client	Marin Post Acute
Sponsor	Medline Industries
Project manager	Robert Taylor Martin, Jr.
Team	Caitlyn Jacobe Dixon-Martin, Dr. Gita Surti, Dr. Eena Duggal, Dr. Anupama Velpuri, and Dr. Razia Rangwala

Evaluation

In this randomized controlled trial (RCT), with a completion date of Friday, April 5, 2024, the elements of the treatment being evaluated are tested for how well it achieves its objectives, as measured by a predetermined set of indicators. The study consists of a randomized controlled, open-labeled, and follow-up phase to recognize the potential value and support to develop capacity for commissioning. As a result:

- What are the ethical and practical limitations?
- When is it appropriate to use this method?
- Which other methods work well?
- What are the challenges?
- Do approaches promote increased awareness?
- How long does it take for the patient to be influenced by these factors?

Endorsements

- Michael J. Fox Foundation for Parkinson's Research, Grand Central Station, P.O. Box 4777, New York, NY 10163-4777 (The Michael J. Fox Foundation for Parkinson's Research, *n.d.).*
- Parkinson's Victoria, 587 Canterbury Rd. Surrey Hills VIC 3127, Australia

- National Parkinson's Foundation (Miami Office), 200 SE 1st Street, Ste., 800, Miami, FL 33131 (Parkinson's Victoria, n.d.)
- American Parkinson's Disease Association, 9940 Talbert Avenue, Fountain Valley, CA 92708 (APDA, n.d.)
- European Parkinsons Disease Association,4 Golding Road, Sevenoaks, Kent TN13 3NJ, United Kingdom (EPDFA, n.d.)

Next Steps

Wearable technologies have evolved gradually in parallel with technological advancements such as electronic chips, GPS systems, Wi-Fi systems, the internet, computers, and sensors. Wearable technologies' significant applications are in the health, textile, and consumer electronics industries. Today, wearable technology diffusion is just at the early adopter stage for society and companies. However, the evolution of wearable technologies, smart glasses, and smartwatches will almost be completed in their revolutions, and communities and companies will adopt these technological devices.

Conclusion

Standard methods used to assess cognitive function in patients with PD often use instructions to direct attention, gauge task difficulty, and measure only the output of the patient's behavioral response. Because this may focus on observable functions and periods when patient comprehension is not compromised, the present study presented stimuli without instruction, manipulated task difficulty by varying stimulus factors, and used the brain's electrical response as the dependent variable. The Motion Watch8, tri-axial accelerometers for automated recording in event-related potentials during passive cognitive tasks in patients with Parkinson's, such as paper and pencil isolated functions, maintaining performance in activities of daily living (ADL), and social functioning, showed good accuracy and validation. However, future developments

could incorporate this sensor arrangement capable of fall detection and mobility monitoring, broadcast and GPS locate like a mobile phone, alerts through radio, TV, road signs, and other data-enabled devices upon detecting a fall. Finally, motion sensor data can be used as a basis for such interventions and as patient feedback.

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