Sample Application for Small Business Funding

Through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, NIA aims to help small businesses develop effective treatments and interventions for healthy aging. NIH small business funding is competitive, and resubmissions are a common and important part of the award process.

Find more NIA sample applications and information about SBIR/STTR funding:
https://www.nia.nih.gov/research/sbir/nia-small-business-sample-applications

PI: **Wang, Victor**	Title: A Specialized Automatic Speech Recognition and Conversational Platform to Enable Socially Assistive Robots for Persons with Mild-to-Moderate Alzheimer's Disease and Related Dementia	
Received: 04/05/2018	FOA: PAR18-186 Clinical Trial:Optional	Council: 08/2018
Competition ID: FORMS-E	FOA Title: Development of Socially-Assistive Robots (SARs) to Engage Persons with Alzheimer's Disease (AD) and AD-Related Dementias (ADRD), and their Caregivers (R43/R44 Clinical Trial Optional)	
1 R44 AG062014-01	Dual:	Accession Number: 4159403
IPF: 10046050	Organization: CARE.COACH CORPORATION	
Former Number:	Department:	
IRG/SRG: ZRG1 ETTN-G (12)B	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A) Year 1: [redacted] Year 2: [redacted] Year 3: [redacted]	Animals: N Humans: Y Clinical Trial: N Current HS Code: 30 HESC: N	New Investigator: Early Stage Investigator:
Senior/Key Personnel:	*Organization:*	*Role Category:*
Victor Wang	CARE.COACH CORPORATION	PD/PI
Shuo Deng	CARE.COACH CORPORATION	Co-Investigator
Brittany Wang	CARE.COACH CORPORATION	Co-Investigator
[redacted]	Pace University	Consultant
[redacted]	Pace University	Consultant
Malaz Boustani	Regenstrief Institute & Indiana University	Co-Investigator

OMB Number: 4040-0001
Expiration Date: 10/31/2019

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE	State Application Identifier

1. TYPE OF SUBMISSION*

❍ Pre-application ● Application ❍ Changed/Corrected Application

4.a. Federal Identifier

b. Agency Routing Number

2. DATE SUBMITTED | **Application Identifier**

c. Previous Grants.gov Tracking Number

5. APPLICANT INFORMATION

Organizational DUNS*: [redacted]

Legal Name*: CARE.COACH CORPORATION
Department:
Division:
Street1*: [redacted]
Street2:
City*: [redacted]
County:
State*: [redacted]
Province:
Country*: [redacted]
ZIP / Postal Code*: [redacted]

Person to be contacted on matters involving this application

Prefix: First Name*: Victor Middle Name: Last Name*: Wang Suffix:

Position/Title: CEO
Street1*: [redacted]
Street2:
City*: [redacted]
County:
State*: [redacted]
Province:
Country*: [redacted]
ZIP / Postal Code*:
Phone Number*: [redacted] Fax Number: Email: [redacted]

6. EMPLOYER IDENTIFICATION NUMBER *(EIN) or (TIN)** [redacted]

7. TYPE OF APPLICANT* R: Small Business

Other (Specify):
Small Business Organization Type ❍ Women Owned ● Socially and Economically Disadvantaged

8. TYPE OF APPLICATION*

● New ❍ Resubmission
❍ Renewal ❍ Continuation ❍ Revision

If Revision, mark appropriate box(es).

❍ A. Increase Award ❍ B. Decrease Award ❍ C. Increase Duration
❍ D. Decrease Duration ❍ E. Other *(specify)* :

Is this application being submitted to other agencies?* ❍Yes ●No What other Agencies?

9. NAME OF FEDERAL AGENCY*
National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
A Specialized Automatic Speech Recognition and Conversational Platform to Enable Socially Assistive Robots for Persons with Mild-to-Moderate Alzheimer's Disease and Related Dementia

12. PROPOSED PROJECT

Start Date* Ending Date*
01/01/2019 06/30/2021

13. CONGRESSIONAL DISTRICTS OF APPLICANT
CA-014

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: First Name*: Victor Middle Name: Last Name*: Wang Suffix:
Position/Title: Chief Executive Officer
Organization Name*: CARE.COACH CORPORATION
Department:
Division:
Street1*: [redacted]
Street2:
City*: [redacted]
County:
State*: [redacted]
Province:
Country*: [redacted]
ZIP / Postal Code*:
Phone Number*: [redacted] Fax Number: Email*: [redacted]

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested* [redacted]
b. Total Non-Federal Funds* [redacted]
c. Total Federal & Non-Federal Funds* [redacted]
d. Estimated Program Income* [redacted]

16.IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?*

a. YES ○ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE:

b. NO ● PROGRAM IS NOT COVERED BY E.O. 12372; OR

○ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

● I agree*

** The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION File Name:

19. AUTHORIZED REPRESENTATIVE

Prefix: First Name*: Victor Middle Name: Last Name*: Wang Suffix:
Position/Title*: CEO
Organization Name*: CARE.COACH CORPORATION
Department:
Division:
Street1*: [redacted]
Street2:
City*: [redacted]
County:
State*: [redacted]
Province:
Country*: [redacted]
ZIP / Postal Code*:
Phone Number*: [redacted] Fax Number: Email*: [redacted]

Signature of Authorized Representative*
Victor Wang

Date Signed*
04/05/2018

20. PRE-APPLICATION File Name:

21. COVER LETTER ATTACHMENT File Name:

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 03/31/2020

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ○ Yes ● No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

○ Yes ○ No

If "No" to AVMA guidelines, describe method and provide scientific justification

2. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

PHS 398 Cover Page Supplement

3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

❑ Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

4. Inventions and Patents Section (Renewal applications)

*Inventions and Patents: ○ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

5. Change of Investigator/Change of Institution Section

❑ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

Tracking Number: GRANT12604831 Funding Opportunity Number: PAR-18-186 . Received Date: 2018-04-05T19:30:51.000-04:00

Abstract
1 in 3 seniors in the United States dies with dementia, of which Alzheimer's disease (AD) is the most common form. AD patients suffer from decreased ability to meaningfully communicate and interact, which causes significant stress and burden for both professional caregivers and family members. Socially assistive robots (SARs) have been designed to promote therapeutic interaction and communication. Unfortunately, artificial intelligence (AI) has long been challenged by the speech of elderly persons, who exhibit age-related voice tremors, hesitations, imprecise production of consonants, increased variability of fundamental frequency, and other barriers that can be exacerbated by the neurological changes associated with AD, further complicated by common environmental noises such as the ceiling fan, television, etc. Because of the resulting poor real-world speech and language understanding by available SAR technologies, scarce human caregivers are often required to guide AD patients through SAR interactions, limiting SARs to small deployments, mostly as part of research studies. Unlike existing approaches relying purely on AI, care.coach™ is developing a SAR-like avatar that converses with elderly and AD patients through truly natural speech. Each avatar is controlled by a 24x7 team of trained human staff who can cost-effectively monitor and engage 12 or more patients sequentially (2 simultaneously) through the audio/visual feeds from the patient's avatar device. The staff communicate with each patient by sending text commands which are converted into the avatar's voice through a speech synthesis engine. The staff contribute to the system their human abilities for speech and natural language processing (NLP) and for generating free-form conversational responses to help patients build personal relationships with the avatar. The staff are guided by a software-driven expert system embedded into their work interface, which is programmed with evidence-based prompting and protocols to support healthy behaviors and self-care. This SBIR Fast-Track project will leverage the unique data generated by our human-in-the-loop platform to develop new ASR capabilities, enabling fully automatic conversational protocols to engage and support AD patients without human intervention. We aim in Phase I to leverage our unique prior work dataset to train an automatic speech recognition (ASR) engine to enable the understanding of certain types of elderly and AD patient speech more successfully than any currently available engine. We aim in Phase II to incorporate this new engine along with an NLP module into our existing human-in-the-loop avatar system, recruiting a population of AD patients to further train and validate with during a 2-year human subjects study so that we can demonstrate full automation of a significant portion of our avatar conversations with mild-to-moderate level AD patients. Thus, we will improve the commercial scalability of our avatars, while validating our new ASR/NLP engine as the most accurate platform for enabling the next generation of AD-focused SARs.

Narrative

Artificial intelligence (AI) has long been challenged by the speech of elderly persons, and especially persons with dementia, due to age-related voice tremors, hesitations, imprecise production of consonants, increased variability of fundamental frequency, and other barriers. Unlike existing approaches to socially assistive robots (SARs) relying purely on limited AI for conversation, care.coach™ has been commercializing a SAR-like avatar that converses with elderly and AD patients through truly natural speech, powered by a 24x7 team of trained human staff. The unique data sets that our solution enables us to gather at commercial scale will be leveraged in this SBIR project to develop an automatic speech recognition (ASR) and natural language processing (NLP) engine that is best-in-class for AD applications, improving the commercial scalability of our avatars by reducing our dependence on human staff, while serving as a new AI platform for enabling the next generation of AD-focused, conversational SARs.

BIOGRAPHICAL SKETCH
DO NOT EXCEED FIVE PAGES.

NAME: Wang, Victor Hsiang-Sheng

eRA COMMONS USER NAME (credential, e.g., agency login): [redacted]

POSITION TITLE: Chief Executive Officer

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of British Columbia	B.A.Sc.	05/2010	Mechatronics (Commerce Minor)
Harvard Business School	N/A	12/2011	Strategy & Technology
Massachusetts Institute of Technology	M.S.	02/2012	Controls, Instrumentation & Robotics

A. Personal Statement

I have the expertise, leadership, training, and motivation necessary to successfully serve as PI on the proposed research project. I have a broad background in robotics and human-machine interaction, with specific training and expertise in teleoperation, medical devices, human subjects and clinical research. My research includes work with hospitals and IRB-approved study protocols. As an awardee or key consultant on several university- and externally-funded grants, I helped to develop much of the groundwork for the proposed research by conceptualizing the techno-organizational platform required to scale a human-software hybrid avatar solution, and established strong ties with healthcare providers and academia which make it possible to recruit future study participants and measure outcomes, as documented in the following publications. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and helped produce several peer-reviewed publications from these projects. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget.

For the current proposal, I will build on my prior work to administer the project's staffing, intellectual property protection, and budget, to collaborate with care.coach technical staff and Regenstrief researchers to develop and validate our new technology, and to disseminate our work. As our organization's Privacy and Information Security Officer, I will also ensure that relevant institutional policies are upheld.

B. Positions and Honors

Positions and Employment

2006-2007 Lakes Research Assistant, UBC Department of Earth and Ocean Sciences, Vancouver, BC
2007-2007 Manufacturing Engineering, Avcorp Industries, Delta, BC
2007-2007 Mechanical Engineering, TRIUMF Research Labs, Vancouver, BC
2008-2008 Reliability Engineering, Suncor Energy, Fort McMurray, AB
2009-2009 Medical Devices Mechatronics Engineer, UBC Robotics & Controls Lab, Vancouver, BC
2006-2010 Electrical & Mechanical Engineering Officer, Canadian Forces, Richmond, BC
2010-2011 Research Assistant, MIT Department of Aeronautics & Astronautics, Cambridge, MA

2011-2012 Teaching Assistant, MIT Department of Mechanical Engineering, Cambridge, MA
2012- Chief Executive Officer, care.coach corporation, Millbrae, CA

Other Experience and Professional Memberships

2011-2012 Executive Committee Member, MIT Graduate Student Council
2012-2012 Entrepreneur, Blueprint Health
2013-2016 Member, Speaker & Reviewer, Gerontological Society of America
2014-2016 Member & Speaker, American Society on Aging
2014- Academy Member, Aging2.0
2015- Guest Lecturer, Stanford University GSB & Stanford University CERC
2016- Guest Lecturer & Mentor, Texas Medical Center Biodesign Fellowship Program

Honors

2010 Wesbrook Scholar, University of British Columbia
2010 Alexander Graham Bell Canada Graduate Scholarship (declined), NSERC
2013 Speaker, TED MED
2012-2016 Speaker, Connected Health Symposium
2015-2016 Speaker, Stanford Medicine X
2017- Speaker, Hospital Elder Life Program

C. Contribution to Science

1. My early involvement in research was as an engineering student, analyzing lake water samples and operating instrumentation for environmental research at the University of British Columbia (UBC). I also contributed to the successful installation and testing of a new multi-charge ion source that increased the capabilities of the isotope separator and accelerator at TRIUMF, a leading particle physics research facility. Then, as a student at the UBC Robotics & Controls Lab, while developing software and electronic systems for a prostate brachytherapy robot to improve treatment of prostate cancer, I also prototyped novel mechanical and hydraulic methods of excitation for ultrasound elastography, contributing to best practices around hand-held transducer design for better detection of breast cancer. Later, as a graduate student at the Massachusetts Institute of Technology, funded by a National Space Biomedical Research Institute (NSBRI) grant, I designed novel neuromotor tests to quantify the bimanual cross-coupling and ergonomic characteristics of manual control devices used in NASA's telerobotic space operations, contributing to the field additional considerations for better telerobotic controller design and guidelines for astronaut training to maximize performance and safety by minimizing neuromotor errors. I also assisted other research, including a [redacted] clinical study at Brigham & Women's Hospital to quantify the effects of fatigue and certain countermeasures on human performance.

    a. Jayamanna, K., Wight, G., Gallop, D., Dube, R., Jovicic, V., Laforge, C., Marchetto, M., Leross, D., Louie, R., Laxdal, R., McDonald, M., Wiebe, G.J., **Wang, V.**, and Yan, F. (2010). A multicharge ion source (Supernanogan) for the OLIS facility at ISAC/TRIUMF. *Review of Scientific Instruments*, 81(2), 02A331.
    b. Liu, A., **Wang, V.**, Forman, R. E., Galvan, R. C., Natapoff, A., and Oman, C. M. (2012). Advanced Displays for Efficient Training and Operation of Robotic Systems. *NASA Human Research Program Investigators' Workshop*, Houston, TX.
    c. **Wang, V.** (2012). Bimanual cross-coupling in space telerobotics (*Master's dissertation, Massachusetts Institute of Technology*).

2. As an entrepreneur, I led the development and dissemination of a class of technology-enabled psychosocial interventions for older adults in the community, largely branded as "GeriJoy" until 2016 The intervention is novel in its combination of multiple evidence-based solutions, including simulated pet therapy and human-controlled avatar interaction. It is also novel in its "back-end" platform, allowing commercial deployment and cost-effective scaling of individualized psychosocial support in a way that no other solution has been able to achieve. Researchers at many universities have been eager to leverage our platform to test their hypotheses around interactive communications, social support, and avatar technology for older adults. The outcomes that we have shown so far include improved perception of social

support and reduced loneliness, as well as indications of benefits for anxiety and depression. Our partners that have published papers about GeriJoy include Pace University and University of Washington, and we have additional research collaborations ongoing with institutions including Stanford University, University of Massachusetts at Lowell, University of Southern California / Palmetto Health, etc. I have been invited to speak about our contributions to the field at such venues as TED MED, Stanford Medicine X, etc. I was recently invited by Springer Publishing to author a textbook chapter about social robots, avatars, and similar interventions for the care of elderly patients.

a. **Wang, V.**, and Shuo, D. (2013). U.S. Patent Application No. 13/939,172.
b. Machesney, D., Wexler, S.S., Chen, T., Coppola, J.F. (2014). Gerontechnology Companion: Virtual pets for dementia patients. *IEEE Long Island Systems, Applications and Technology Conference, Long Island, NY*.
c. Chi, N., et al. (2016). The Usability of a Digital Companion Pet for Older Adults with Mild Cognitive Impairment. *Gerontological Society of America's 69th Annual Scientific Meeting, New Orleans, LA, USA*.
d. Demiris, G., Thompson, H.J., Lazar, A., & Lin, S.Y. (2016). Evaluation of a Digital Companion for Older Adults with Mild Cognitive Impairment. *American Medical Informatics Association 40th Annual Symposium.*
e. **Wang V.H.S.**, Luxenberg J, & Morey, R. (2016). care.coach: Healing the Patient by Supporting the Person. *National PACE Association Annual Conference*, San Francisco, CA.
f. Chi, N., Sparks, O., Lin, S., Lazar, A., Thompson, H.J., Demiris, G. (2017). Pilot testing a digital pet avatar for older adults. *Geriatric Nursing.*
g. **Wang V.**, and Osborne T.F. (2017). Relational agents: Technologically Enabled Psychosocial Support for Improved Healthcare. In: Chau, D. & Osborne, T.F. Eds. *Health Technology for Older Adults*. Springer Publishing Company.
h. **Wang V.** & Seavey, K. (2017). Integrating Innovative Technology in the Home to Provide Enhanced Continuity of Care and Decreased Healthcare Costs for Older Adults. Poster session presented at *National PACE Association Annual Conference*, Boston, MA.

3. I have also been engaged in consulting and provision of my company's avatar services for hospital-based research organizations, largely under the "care.coach" brand. I led care.coach to win the [redacted] grant from the [redacted], funding a research study at Jamaica Hospital Medical Center budgeted at [redacted] including in-kind contributions from care.coach and Pace University. For this use case, I continued to lead care.coach to design extensive software systems and algorithms to automate the execution of falls and delirium mitigation protocols based on clinical best practices and established research findings. Our hospital inpatient research findings have been presented at both the University of Texas Community Engagement & Healthcare Improvement Conference and at Aging in America, and a paper is now pending publication. Outcomes include unprecedented 70-85% reduction in fall rate, statistically significant mitigation of delirium and loneliness, and compelling examples of restraint use avoidance.

a. Wexler, S.S., Drury, L. & Pollak, C. (2017a). Tablet-Based Technology Intervention to Improve Outcomes in Hospitalized Older Adults. *International Association of Gerontology and Geriatrics World Congress*, San Francisco, CA.
b. Wexler, S.S., Drury, L. & Pollak, C. (2017b). The Use of an Avatar Virtual Service Animal to Improve Outcomes in Hospitalized Older Adults. *NICHE Annual Conference*, Austin, TX.
c. **Wang, V.**, Wang, B. (2018). Culturally Adaptive Digital Avatars for Psychosocial and Self-Management Support of High Risk Elders. *Aging in America*.

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

NIH R24AG054259 Inouye (PI) 2016-
Collaborative Networks to Advance Delirium Research
The goal of this study is to support a collaborative network to advance scientific research on the causes, mechanisms, outcomes, diagnosis, prevention, and treatment of delirium in older adults.
Role: Dissemination Task Force Contributor (Volunteer)

Completed Research Support

NSBRI J08ZSA_7523 Oman (PI) Sep 2011 – Dec 2011
Validation of Assessment Tests and Countermeasures for Detecting and Mitigating Changes in Cognitive Function during Robotics Operations
The goal of this study was to characterize changes in performance during simulated robotic operations, validate cognitive and drowsiness assessments as predictors of performance, and test the efficacy of fatigue countermeasures (e.g., blue enriched white light, caffeine) to improve cognition during robotic operations.
Role: Research Assistant

NSBRI NASA Contract NCC9-58 Oman (PI) Sep 2011 – Feb 2012
Bimanual cross-coupling in space telerobotics
The goal of this project was to quantify the bimanual cross-coupling and ergonomic characteristics of manual control devices used in NASA's telerobotic space operations, contributing knowledge of telerobotic controller design and astronaut training to maximize performance and safety by minimizing neuromotor errors.
Role: Research Assistant

[redacted] [redacted] Jan 2013 – Dec 2013
'I am Dougie, your virtual service dog': An Intervention to Address Loneliness in Older Adults
The goal of this study was to assess a community-based avatar intervention for providing psychosocial and chronic condition self-management support for high-risk older patients discharged from the hospital.
Role: Consultant

[redacted] Garrison (PI) Feb – May 2016
GeriJoy Versus Usual Care for ACTT Patients: a Pilot Study
The goal of this study was to assess a community-based avatar intervention for providing psychosocial and chronic condition self-management support for high-risk older patients discharged from the hospital.
Role: Consultant

[redacted] [redacted] Feb – Aug 2016
Use of an Avatar-Enhanced Care Team to Improve Outcomes in Hospitalized Older Adults
The goal of this study was to assess a hospital-based avatar intervention for providing psychosocial support to older inpatients, while executing evidence-based protocols to reduce falls and delirium risk. The study was conducted by Pace University nursing professors at Jamaica Hospital Medical Center in Queens, NY.
Role: Consultant

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 1

ORGANIZATIONAL DUNS*: [redacted]

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: CARE.COACH CORPORATION

Start Date*: 01-01-2019 **End Date*:** 06-30-2019 **Budget Period:** 1

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .		Victor		Wang		PD/PI	[redacted]	[redacted]			[redacted]	[redacted]	[redacted]
2 .	Dr.	Shuo		Deng		Co-Investigator	[redacted]	[redacted]			[redacted]	[redacted]	[redacted]
3 .		Brittany		Wang		Co-Investigator	[redacted]	[redacted]			[redacted]	[redacted]	[redacted]

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person [redacted]

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Software Engineer, Machine Learning	[redacted]			[redacted]	[redacted]	[redacted]
1	Software Engineer, Android	[redacted]			[redacted]	[redacted]	[redacted]
2	**Total Number Other Personnel**					**Total Other Personnel**	[redacted]
						Total Salary, Wages and Fringe Benefits (A+B)	[redacted]

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1

ORGANIZATIONAL DUNS*: [redacted]

Budget Type*: ● Project ○ Subaward/Consortium

Organization: CARE.COACH CORPORATION

Start Date*: 01-01-2019 **End Date*:** 06-30-2019 **Budget Period: 1**

C. Equipment Description

List items and dollar amount for each item exceeding [redacted]

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	[redacted]

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	[redacted]
2. Foreign Travel Costs	
Total Travel Cost	[redacted]

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	[redacted]

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 1

ORGANIZATIONAL DUNS*: [redacted]

Budget Type*: ● Project ○ Subaward/Consortium

Organization: CARE.COACH CORPORATION

Start Date*: 01-01-2019 **End Date*:** 06-30-2019 **Budget Period:** 1

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	[redacted]
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Computers	[redacted]
9 . Paid ASR software/service	[redacted]
10 . Server	[redacted]
Total Other Direct Costs	[redacted]

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	[redacted]

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified total direct costs	[redacted]	[redacted]	[redacted]
		Total Indirect Costs	[redacted]

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	[redacted]

J. Fee	Funds Requested ($)*
	[redacted]

K. Total Costs and Fee	Funds Requested ($)*
	[redacted]

L. Budget Justification*	File Name: Budget_Justification.pdf
	(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 2

ORGANIZATIONAL DUNS*: [redacted]

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: CARE.COACH CORPORATION

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period:** **2**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .		Victor		Wang		PD/PI	[redacted]	[redacted]			[redacted]	[redacted]	[redacted]
2 .		Shuo		Deng		Co-Investigator	[redacted]	[redacted]			[redacted]	[redacted]	[redacted]
3 .		Brittany		Wang		Co-Investigator	[redacted]	[redacted]			[redacted]	[redacted]	[redacted]

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person [redacted]

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Software Engineer, Machine Learning	[redacted]			[redacted]	[redacted]	[redacted]
1	Software Engineer, Android	[redacted]			[redacted]	[redacted]	[redacted]
1	Software Engineer, Web	[redacted]			[redacted]	[redacted]	[redacted]
3	**Total Number Other Personnel**					**Total Other Personnel**	[redacted]
						Total Salary, Wages and Fringe Benefits (A+B)	[redacted]

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 2

ORGANIZATIONAL DUNS*: [redacted]

Budget Type*: ● Project ○ Subaward/Consortium

Organization: CARE.COACH CORPORATION

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period:** 2

C. Equipment Description

List items and dollar amount for each item exceeding [redacted]

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	[redacted]

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	[redacted]
2. Foreign Travel Costs	
Total Travel Cost	[redacted]

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	[redacted]

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 2

ORGANIZATIONAL DUNS*: [redacted]

Budget Type*: ● Project ○ Subaward/Consortium

Organization: CARE.COACH CORPORATION

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period:** 2

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	[redacted]
2. Publication Costs	[redacted]
3. Consultant Services	[redacted]
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	[redacted]
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Server	[redacted]
9 . LTE Internet Access	[redacted]
10 . ASR Cloud Service	[redacted]
Total Other Direct Costs	[redacted]

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	[redacted]

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified total direct costs (only first [redacted] of Regenstrief)	[redacted]	[redacted]	[redacted]
Total Indirect Costs			[redacted]

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	[redacted]

J. Fee	Funds Requested ($)*
	[redacted]

K. Total Costs and Fee	Funds Requested ($)*
	[redacted]

L. Budget Justification*	File Name: Budget_Justification.pdf
	(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 3

ORGANIZATIONAL DUNS*: [redacted]

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: CARE.COACH CORPORATION

Start Date*: 07-01-2020 **End Date*:** 06-30-2021 **Budget Period:** 3

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Victor		Wang		PD/PI	[redacted]	[redacted]			[redacted]	[redacted]	[redacted]
2.		Shuo		Deng		Co-Investigator	[redacted]	[redacted]			[redacted]	[redacted]	[redacted]
3.		Brittany		Wang		Co-Investigator	[redacted]	[redacted]			[redacted]	[redacted]	[redacted]

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person [redacted]

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Software Engineer, Machine Learning	[redacted]			[redacted]	[redacted]	[redacted]
1	Software Engineer, Android	[redacted]			[redacted]	[redacted]	[redacted]
1	Software Engineer, Web	[redacted]			[redacted]	[redacted]	[redacted]
3	**Total Number Other Personnel**					**Total Other Personnel**	[redacted]
						Total Salary, Wages and Fringe Benefits (A+B)	[redacted]

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 3

ORGANIZATIONAL DUNS*: [redacted]

Budget Type*: ● Project ○ Subaward/Consortium

Organization: CARE.COACH CORPORATION

Start Date*: 07-01-2020 **End Date*:** 06-30-2021 **Budget Period:** 3

C. Equipment Description

List items and dollar amount for each item exceeding [redacted]

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	[redacted]

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	[redacted]
2. Foreign Travel Costs	
Total Travel Cost	[redacted]

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	[redacted]

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 3

ORGANIZATIONAL DUNS*: [redacted]

Budget Type*: ● Project ○ Subaward/Consortium

Organization: CARE.COACH CORPORATION

Start Date*: 07-01-2020 **End Date*:** 06-30-2021 **Budget Period:** 3

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	[redacted]
3. Consultant Services	[redacted]
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	[redacted]
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Server Rental	[redacted]
9 . LTE Internet Access	[redacted]
10 . ASR Cloud Service	[redacted]
Total Other Direct Costs	[redacted]

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	[redacted]

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified total direct costs (only first [redacted] of Regenstrief)	[redacted]	[redacted]	[redacted]
Total Indirect Costs			[redacted]

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	[redacted]

J. Fee	Funds Requested ($)*
	[redacted]

K. Total Costs and Fee	Funds Requested ($)*
	[redacted]

L. Budget Justification*	File Name: Budget_Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)
Section A, Senior/Key Person	[redacted]
Section B, Other Personnel	[redacted]
Total Number Other Personnel	[redacted]
Total Salary, Wages and Fringe Benefits (A+B)	[redacted]
Section C, Equipment	[redacted]
Section D, Travel	[redacted]
1. Domestic	[redacted]
2. Foreign	[redacted]
Section E, Participant/Trainee Support Costs	[redacted]
1. Tuition/Fees/Health Insurance	[redacted]
2. Stipends	[redacted]
3. Travel	[redacted]
4. Subsistence	[redacted]
5. Other	[redacted]
6. Number of Participants/Trainees	[redacted]
Section F, Other Direct Costs	[redacted]
1. Materials and Supplies	[redacted]
2. Publication Costs	[redacted]
3. Consultant Services	[redacted]
4. ADP/Computer Services	[redacted]
5. Subawards/Consortium/Contractual Costs	[redacted]
6. Equipment or Facility Rental/User Fees	[redacted]
7. Alterations and Renovations	[redacted]
8. Other 1	[redacted]
9. Other 2	[redacted]
10. Other 3	[redacted]
Section G, Direct Costs (A thru F)	[redacted]
Section H, Indirect Costs	[redacted]
Section I, Total Direct and Indirect Costs (G + H)	[redacted]
Section J, Fee	[redacted]
Section K, Total Costs and Fee (I + J)	[redacted]

Tracking Number:

Funding Opportunity Number: . Received Date:

SPECIFIC AIMS

GOAL: This SBIR Fast-Track proposal aligns with NIA's focus on developing artificial intelligence (AI) for socially assistive robots (SARs) to assist families in caring for family members with Alzheimer's disease (AD) and related diseases, and to assist formal care providers helping such families. We aim in Phase I to leverage our unique prior work dataset to train an automatic speech recognition (ASR) engine to enable the understanding of certain types of elderly and AD patient speech more successfully than any currently available engine. We aim in Phase II to incorporate this new engine into our existing human-in-the-loop SAR system, with a substantial real-world pilot population to further train and validate with so that our engine can fully automate a significant portion of conversations with mild-to-moderate stage AD patients.

SIGNIFICANCE: 1 in 3 seniors in the United States dies with dementia. AD is the most common form of dementia, and the number of new cases of AD increases dramatically with age. Because of the aging population in the United States, the annual number of new cases of AD is projected to double by 2050 [Alzheimer's Association, 2014; Dudgeon, 2010]. AD patients suffer from decreased ability to meaningfully communicate and interact, which causes significant stress and burden for both professional caregivers and family members [World Health Organization, 2012]. Thus, as an alternative approach, SARs are designed to promote therapeutic interaction and communication [Feil-Seifer, 2011; Roger, 2012]. Preliminary results show positive reactions of AD patients to SARs, but AI has long been challenged by the speech of elderly persons, who exhibit age-related voice tremors, hesitations, imprecise production of consonants, increased variability of fundamental frequency, and other barriers that can be exacerbated by AD, and by environmental noises such as the ceiling fan, television, etc [Vacher, 2015; Kwon, 2016]. Because of the limitations of these solutions (e.g., poor speech and language understanding by the SAR, requiring scarce human caregivers to guide the patient through the SAR interaction), SARs have been limited to small deployments, mostly as part of research studies [Mordoch, 2013].

APPROACH: Unlike existing patient engagement systems [Sidner, 2014; Abbott, 2016] that require computer skills such as typing, pressing buttons to indicate a response, speaking very clearly, and using specific keywords/phrasing, care.coach™ is developing a SAR-like avatar that converses with elderly and AD patients through truly natural speech. Each avatar is controlled by a 24x7 team of trained human staff who can cost-effectively monitor and engage 12 or more patients sequentially (2 simultaneously) through the audio/visual feeds from the patient's avatar device. The staff communicate with each patient by sending text commands which are converted into the avatar's voice through a speech synthesis engine. The staff contribute to the system their human abilities for speech and natural language processing (NLP) and for generating free-form conversational responses to help patients build personal relationships with the avatar. The staff are guided by a software-driven expert system embedded into their work interface, which is programmed with evidence-based prompting and protocols to support healthy behaviors and self-care. This SBIR project will leverage the unique data generated by our human-in-the-loop platform to develop new ASR capabilities, enabling fully automatic conversational protocols to engage and support AD patients without human intervention.

PRIOR WORK: Our academic partners from University of Washington & Pace University have conducted multiple studies with the care.coach avatar in community and hospital settings, showing increased social support through informational, affectionate, and positive social interaction mechanisms, decreased loneliness, and decreased depressive symptoms. In a clinical study conducted by Pace University in 2016 at Jamaica Hospital Medical Center with 95 patients, hospitalized elders showed 70-85% reduction in rate of falls, significant reduction in delirium and loneliness metrics, and compelling examples of non-pharmacological avoidance of restraint use through the engagement and redirection from our avatars. care.coach™ also has several commercial contracts with specialized health plans and with the Alzheimer's Association.

PHASE I SPECIFIC AIMS: (1) During our prior work, we collected over 5,000 hours of voice data from our patient-avatar interactions. We will convert this data into a training set matched with transcriptions through an automatic/manual hybrid approach. We will focus on patients' responses to avatar prompts during pre-scripted protocols, when the expected utterances are usually simple and constrained to a limited response set, for example, equivalent to "yes" or "no." **(2)** Using this training set, we will develop a Deep Neural Network (DNN) based ASR model specialized in recognizing the speech of elderly patients in response to such prompting, in real-world home and eldercare situations, with a Word Error Rate (WER) of [redacted] representing a practically usable solution for AD SAR applications.

PHASE II SPECIFIC AIMS: (1) Our prior work showed that elderly patients often utter free-form responses even when the expected answer is as simple as "yes" or "no." Thus, we will develop a keyword matching NLP module to comprehend semantically similar phrases, so that patients can interact with the system more naturally, with intent parsing success rate of over 90%. **(2)** To handle particularly challenging speech recognition tasks, especially when interacting with AD patients, we will integrate the new ASR/NLP modules into our human-in-the-loop avatar platform, by developing a new human/AI hybrid system that dispatches low-confidence machine recognition tasks (less than 30% of cases) to be handled by our human staff. This system will also enable these machine recognition tasks to be manually labeled by our staff, enabling continuous DNN model tuning. **(3)** We will conduct additional real-world training and validation of the abovementioned techniques with 200 mild-moderate AD patients through Regenstrief Institute, each patient interacting with their avatar in their home for up to 2 years. The conversational data will be used to further tune the DNN models at both the AD population and individual level (including as the disease progresses for each patient). We will measure the proportion of pre-scripted conversational protocols automatically executed vs. aided by human staff, with a goal of fully automating [redacted] total avatar interaction while maintaining equal or better usability and satisfaction measures compared to the human-reliant system developed in our prior work. Our Phase II work product will therefore [redacted] and will represent a licensable, best-in-class ASR solution that will enable a new generation of useful SARs for persons with AD.

RESEARCH STRATEGY

1. SIGNIFICANCE

1.1. Problem to be Solved

The number of older Americans has increased rapidly, by 11.1 million or 30% from 2005 to 2015, compared to an increase of only 5.7% for the under-65 population [US Department of Health and Human Services, 2016]. Because of the tremendous shortage on staff and qualified healthcare personnel, as well as seniors' increasing preference to live in their own homes as long as possible instead of being institutionalized, there is growing need for Social Assistive Robots (SARs) to assist in their daily lives [Broekens, 2009]. Preliminary results show positive reactions of seniors to SARs, but AI has long been challenged by the speech of elderly persons, who exhibit age-related voice tremors, hesitations, imprecise production of consonants, increased variability of fundamental frequency, and by environmental noises such as the ceiling fan, television, etc. [Vacher, 2015; Kwon, 2016]. Neurological changes to speech are particularly problematic in persons with Alzheimer's disease (AD), the most common form of dementia, affecting 1 in 3 elderly deaths. The number of new cases of AD increases dramatically with age, and because of the aging population in the United States, the annual number of new cases of AD is projected to double by 2050 [Alzheimer's Association, 2014; Dudgeon, 2010]. AD patients suffer from decreased ability to meaningfully communicate and interact, which causes significant stress and burden for both professional caregivers and family members [World Health Organization, 2012], and brings significant challenges in speech recognition for SAR systems designed to promote therapeutic interaction and communication [Feil-Seifer, 2011; Roger, 2012]. Because of the limitations of poor speech and language understanding of existing SAR solutions, such SARs have been limited to small deployments, mostly as part of research studies [Mordoch, 2013]. In this proposed project, we propose to design and develop techniques to improve the usability of SARs, especially the ones designed to be communicative through verbal conversation with persons with AD.

1.2. Existing Solutions

Earlier research efforts in the SAR area focused on pet-like robots that provide companionship by interacting with patients through audio, visual, and tactile signals [Mordoch, 2013]. A few of the most widely used robots include AIBO [Fujita, 2001], Paro [Wada, 2007], and iCat [Breemen, 2005]. However, due to the limited functionality of the robots, as well as the high cost for physical robot hardware, previous studies have been limited in both number of participants and length of study [Broekens, 2009; Mordoch, 2013]. Also, most of the robots have been designed for research use, with limited commercial impact in the healthcare industry.

In recent years, advances in artificial intelligence have enabled computers to understand human speech and to conduct verbal conversations. Related techniques have been applied to SAR related systems, [redacted] However, researchers have found that while these types of virtual assistant SARs can perform some tasks in an acceptable manner, they are limited in their ability to make complex judgements [Abbott, 2016].

1.3. Prior Work at care.coach

The care.coach corporation is developing a SAR platform that provides 24x7 proactive patient support in a more effective and lower cost way than any previously available solution applicable to an AD patient population. Our patient-facing interface appears as a virtual animal avatar on a specialized touch-screen Android tablet configured for use either in the hospital or at home (Figure 1). Patients interact with the avatar by speaking with it or touching it. This interface allows even elders who have functional impairments or dementia to be engaged effectively in a joyful way, regardless of ability or technical inclination.

Figure 1. The avatar gives encouragement for a patient to take medications at home (left). The avatar plays a Frank Sinatra song and shows a photo for a hospitalized elder (right).

Our avatars are controlled by a remote team of “health advocates” who use our proprietary online interface to monitor and engage multiple patients at a time (Figure 2, left). Health advocates contribute to the system their human abilities for natural language understanding and compassionate conversational responses to help each avatar build a personal relationship with its patient. Additionally, the abilities of the health advocates are augmented through a software-driven expert system embedded into their work interface, which guides them through evidence-based, pre-scripted clinical protocols, for example to mitigate falls and delirium in the hospital by executing cognitive exercises, re-orientation, and toileting checks, and alerting the nurse station of any issues requiring action. These protocols are programmed using an administrative interface (Figure 2, right).

[redacted]

Figure 3. Two screen snips from the Provider Portal show individual patient self-management data for various risk mitigating protocols executed at home (left, top) and patient risk stratification across a pool of enrolled patients using data obtained by the care.coach avatar (left, bottom). Two screen snips from the Family Portal show the ability to add commented family photos for the avatar to engage the patient with (right, top), and health advocate journal entries which provide peace of mind for family members (right, bottom).

1.4. Preliminary Evidence

In a pilot clinical study (Wexler, Drury, Pollak, 2017a; Wexler, Drury, Pollak, 2017b; Wang V, Wang B, 2018) conducted in 2016 by Pace University at Jamaica Hospital Medical Center with 95 elderly, ethnically diverse inpatients, the primary intervention unit which deployed care.coach avatars at the bedside of high-risk patients showed an unprecedented 85% reduction in rate of falls compared to a control unit with a similar patient population during the same time period. Fall rate reduction was 70% compared to historical, pre-intervention data from the intervention unit. The intervention unit showed a 3-month fall rate of only 0.9 falls per 1000-patient days (the national average fall rate of 3.56 falls per 1000 patient-days). Intervention patients also showed a significant reduction in delirium (CAM) and loneliness (UCLA-LS), as well as compelling examples of non-pharmacological restraint avoidance. A partial intervention unit that only deployed avatars for half of the quarterly falls data collection period also experienced a reduction in fall rate compared both to the control unit and to historical data from the same unit. Because the hospital did not have the resources to set up a customized delirium and falls risk screen to indicate suitability for the care.coach intervention within the electronic health record, research assistants (who were nursing students) coordinated with hospital nursing staff to identify older patients who they felt would be suitable due to high subjective risk. Mean age was 76.9 years, with 68.3% female, only 24.4% ethnically white (53.7% African American, 12.2% Asian or Pacific Islander, 7.3% Hispanic), and 39% spoke English as a second language. Typical length of stay was 3-6 days. On average, the avatar checked in (started the audio/video stream, visually waking up the avatar) 71.3 times per day per patient, engaged each patient for 61 minutes per day (including the use of 11.5 images or audio files), and completed 6.5 protocol-driven tasks per day. The primary intervention unit nurse manager was quoted as reporting, “This is a wonderful project. Care.coach is just great. I am thrilled that the study is happening on my unit. It is good for the patients,” and a family member was quoted, “This is just what my mother needed in the hospital.” Hospital staff have tended to assign care.coach avatars to their most challenging patients who, in addition to falls and delirium risk, would normally consume great amounts of staff time due to cognitive or behavioral challenges. Because these preliminary data show that this avatar system has the potential to effectively build psychosocially supportive relationships with frail elders and significantly impact quality of care by eliciting care needs and influencing behavior of frail elders at risk for delirium, we believe that with additional research and validation, such an avatar-enabled solution has the potential to drive enormous clinical quality and cost containment impact in the field of cognitive impairment care.

Our academic partners, including Pace University and University of Washington, have also conducted studies showing increased social support (MOS-SSS), decreased depressive symptoms (PHQ-9), and decreased loneliness (UCLA-LS) in the community, among older adults with varied socioeconomic status and cognitive function living at home or in non-medical long-term care (Chi, Demiris, Thompson, Lazar & Lin, 2016; Demiris, Thompson, Lazar & Lin, 2016; Machesney, Wexler, Chen & Coppola, 2014).

In addition to these research efforts, our company already has hospital and PACE health plan customers that report positive quality improvement results (Wang, Luxenberg & Morey, 2016; Wang & Seavey, 2017). Patient satisfaction has been high, with 95% of patients reporting they would recommend care.coach to a friend. Staff acceptance is also high, with 88% of care coordinators reporting that they would recommend care.coach for their own parents. We also have a commercial contract with Alzheimer’s Association (see support letters).

1.5. Value of Proposed SBIR Project

Presently, our health advocates interpret all audio/visual feeds. All avatar speech is either typed out by our health advocates to be spoken by the avatar or is part of a pre-scripted protocol that a health advocate must approve at every step. [redacted]

[redacted]. Thus, our long-term plan is to design and develop a human-in-the-loop system in which the AI can conduct rudimentary interactions while generating a confidence score for its interaction capability in real-time. The AI will automatically interact with the patient when the confidence score is high, and will dispatch the interaction to a health advocate when the confidence score is low. In this way, the system can reduce the amount of human intervention required, increasing the reliability of responses for structured conversations (e.g. self-management reminders), and decreasing the response delay caused by human factors.

In recent years, AI-powered virtual personal assistants have rapidly developed. Impactful products such as Amazon Echo, Google Assistant, Apple Siri and so on have been proven to be commercially successful. However, the usability of virtual personal assistant for elderly populations, including AD patients, remains a challenging problem [Vollmer, 2017]. Our well-defined use case and proprietary dataset enable us to further improve the technology for these real-world, underserved populations and environments, as well as demonstrating feasibility of virtual assistant technology in healthcare systems serving the highest need, highest risk patients. Not only will the proposed SBIR work directly improve our own product platform at care.coach, but also we plan to license the resulting engine to help enable other SAR solutions targeting persons with AD.

2. INNOVATION

2.1. Human-in-the-Loop SAR System Design

Unlike our competitors described in Section 1.2, who rely purely on artificial intelligence to interact with patients, our goal is to develop a human-in-the-loop AI system, in which simple tasks will be handled by AI automatically, and complex judgement will be dispatched to humans. This design enables our system to be commercialized more readily for complex patient populations and healthcare applications by bringing much more value than a pure AI solution. By enabling use cases that are more complex than pure AI solutions are capable of handling, we will also begin to gather valuable training data that would otherwise be unavailable, to further the capabilities of AI in healthcare and dementia care applications.

In our existing system, the use of virtual animal avatar at the front-end ensures consistent appearance and behavior on the patient side 24x7, despite shift changes of our remote team members. This consistency helps to build a strong relationship between the patient and the avatar, and eliminates the usual confusion caused when patients, particularly those with memory impairment, must interact with multiple caregivers at different times of the day/week. Our health advocates are currently hired through [redacted]. They are required to pass a background check, are psychometrically screened, and have a minimum set of certifications such as training in dementia care, privacy and ethics, motivational interviewing, and more. Most them are located in the Philippines and Latin America. The verbal commands sent out by the health advocates are transferred to the avatar in text format, and then converted into avatar's voice through text-to-speech (TTS) technology. This text-to-speech conversion leverages commercially available (e.g. via Google), constantly improving TTS engines to read out text in a natural-sounding voice. Using TTS instead of having the health advocates talking with patients directly ensures that each avatar has a voice that is consistent across health advocate shift changes, and that the selected voice can be configured to speak in a suitable American English accent (or American Spanish, for Spanish speaking users). The pitch and speech rate of each avatar's voice are also configurable to meet the patient's preference and hearing needs. For example, a lower pitch may be preferred for patients with hearing impairment.

2.2. Long-Term Service for Progressive Learning

Our system has been deployed for various research studies. Participants of the studies showed strong interest and desire to continue our service after the studies were done, demonstrating our system's capability to

provide long-term interpersonal support, which is a significant improvement compared to previous work which suffered from an inability to conduct long-term studies due to the limited functionality and long-term appeal of the SAR [Broekens, 2009]. From an AI perspective, this long-term relationship enables our system to train machine learning models that can be highly personalized, as the system can gather more and more data for each individual patient, particularly as their AD or related dementia inevitably progresses and speech/cognitive patterns change. Developing an engine for speech understanding in the context of a long-term psychosocial relationship offers unique opportunities to study and improve SAR efficacy to match the progression of the disease across stages.

2.3. Novelty & Intellectual Property

[redacted]

3. APPROACH

In our existing system, the interaction between the avatar and the patient can be either a free form conversation fully controlled by our remote health advocates, or a pre-scripted, health-related protocol conversation which needs the health advocate to aid the progress. In this SBIR project, our goal is to implement the above-mentioned human-in-the-loop SAR system for pre-scripted protocol conversations. These protocols use branching logic and pre-scripted conversational content to guide patients through various intervention protocols, already deployed in our system to support chronic condition self-management for patients living at home, and to support fall and delirium prevention for hospitalized elders, for example by executing cognitive engagement/assessment, re-orientation, toileting checks, and so on. A simple example of a branching protocol could be as shown in Figure 4.

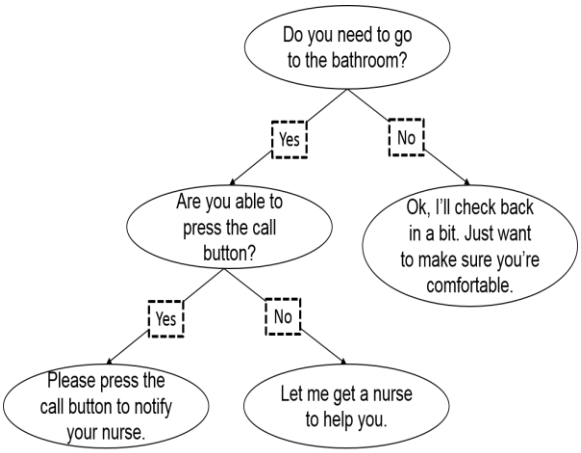


Figure 4. A simple example of a pre-scripted fall prevention protocol. The text in the branching tree nodes (shown in ovals) are the pre-scripted sentences to be spoken by the avatar. The text in the branching conditions (shown in dashed rectangles) are the expected answers from the patient, which can trigger different avatar responses.

There main reasons that we decided to focus on these pre-scripted protocols as our first step towards a fully functional human-in-the-loop SAR system are twofold: 1) for each of the protocols, the conversations are initiated by the avatar with pre-scripted sentences, which gives the system an accurate trigger to start speech recognition. 2) The expected responses from the patients are usually short and can be contained in a limited speech data corpus. For instance, the above example protocol only expects a “Yes” or “No” answer from the patient. These two characteristics of the pre-scripted protocol conversations make the speech recognition problem much more well-defined, compared to general, free-form conversations. Moreover, based on our internal data analyses, the pre-scripted protocol conversations take up 40% of the total interaction between the patient and the avatar. Successfully implementing the system in this way can thus significantly reduce the amount of human intervention required for the whole system and make our business model more scalable.

Although pre-scripted protocol automation is a well-defined problem, it is challenging and cannot be fully resolved by simply using off-the-shelf speech recognition engines. In a preparatory project (described in section 3.1) with our internal speech data, the most up-to-date Google speech recognition engine was only able to achieve a word error rate (WER) of 33% when recognizing patients' speech in pre-scripted protocol conversations. By investigating the failed recognition samples, we found the aforementioned challenges related to speech characteristics of elderly persons [Vacher, 2015] and environmental noises such as the ceiling fan, television, etc. requiring a noise-robust speech recognition engine [Li, 2014]. Besides these two challenges, in certain cases, successfully recognizing the word may not achieve protocol automation. For example, although the expected responses are limited, the patients' actual response can be variable. In the above bathroom check protocol, the system is expecting a "Yes" answer from the patient, however, if the patient says "Sure" or "I thought you'd never ask," which have very similar meanings semantically, a simple speech recognition system would not be able to guide our system to go to the correct branch of the pre-scripted conversation in all cases: basic natural language processing (NLP) keyword extraction techniques [Dostal, 2011] also need to be implemented.

The development of the human-in-the-loop system is based on a combination of user data, with and without AD. Once a prototype of the system is developed in Phase I, we plan to conduct a human subjects research study with an AD patient population to further refine our engine and to validate its live, real-world performance. With the capability of online learning embedded in our system, it will continuously improve the system using new data.

In summary, this proposed SBIR project will automate our pre-scripted protocol conversations by developing an ASR engine based on our proprietary corpus, as well as by building a dispatch system to hand off conversation to human health advocates when the conversation goes beyond AI capability. Successful completion of this project will increase our business scalability, while developing an engine that can enable other SAR solutions for older adults and persons with AD.

3.1. SBIR Preparatory Project

During our prior work described in Section 1.4, we collected [redacted] of voice data from patient-avatar interactions. This dataset will be leveraged for our SBIR Phase I and II studies. Prior to this proposed SBIR project, we conducted a preparatory project to validate the feasibility of our proposed methods as well as understand the performance baseline of our proposed system. We randomly selected [redacted] of interaction recordings, and manually separated the pre-scripted protocol conversations from free-form conversation. After the separation, we found [redacted] of pre-scripted conversation, which takes up 48% of the raw data. Because all commands sent from the health advocates to the avatar to be spoken out are stored in our database in text format, we ran database queries to calculate the number of total words spoken by the avatar in pre-scripted conversations as well as in free-form conversations. The query results showed that across the entire [redacted], 40% of the words spoken by the avatar are pre-scripted. Thus, our randomly selected [redacted] is representative of the larger dataset.

The sub-set of [redacted] of pre-scripted conversation contained both avatar speech and patient speech. Since our goal is for the avatar to understand patient speech, we then separated the audio segments during which the patient is speaking, resulting in [redacted] of audio, or 15% of the raw data. We uploaded this [redacted] dataset to the Google speech recognition engine, and gathered the speech recognition results in the format of recognized text strings with associated confidence scores. Meanwhile, we had humans manually listen to these audio recordings and transcribe them into text, to serve as the ground truth of what the patients said. Our analysis showed that Google speech recognition engine achieved a 33% word error rate (WER). The errors mostly occur when there is significant background noise, or there is a long delay between words, or the patients have trouble speaking. For the text strings successfully recognized, 60% do not match an expected "Yes" or "No" answer, because the patient answered the question using an unexpected phrase such as "Sure" or "Of course I did …". By having a human read the ASR engine recognized text, we found that over 90% of such unexpected answers' intent (i.e. "Yes" or "No") can be successfully recognized.

3.2. Phase I Research Plan

Building on the latest work in offline, Android-based ASR [Gaida, 2016; Sharma, 2016; McGraw, 2016], we seek to develop a speech recognition engine trained on our proprietary corpus of elder-avatar speech data, representing a larger training set than previously available [Vacher, 2015].

In Phase I, we plan to leverage our [redacted] of proprietary audio recordings, combined with timestamped health advocates' reaction data, to train a Deep Neural Network (DNN) based speech recognition model specialized in recognizing short phrases of elderly individuals in real-world home and eldercare situations subject to environmental noise. By completing Phase I aims, we not only build groundwork for the proposed Phase II work, but also implement a general-purpose speech recognition engine, as well as a labeled training corpus, specially designed for AD patients. Thus, the Phase I work product can potentially create business value independent of Phase II by being licensed to other SAR developers building solutions for AD patients.

3.2.1. Phase I Specific Aim 1: Building a Training Data Set

Overall Strategy: During our prior work, we collected [redacted] of voice data from patient-avatar interactions. We will convert this data into a training set matched with transcriptions through an automatic/manual hybrid approach. We will focus on patients' responses to avatar prompts during pre-scripted protocols, when the expected utterances are simple and usually constrained to a limited vocabulary, e.g., equivalent to "yes" or "no."

Methodology & Analyses: The first step towards automating the avatar's interaction with the patient is to have the system convert the patient's speech from voice audio into text. During our prior work over the past two years, we recorded [redacted] of interaction between the elders and the avatars in the form of audio/video files, in care scenarios ranging from hospital inpatient care to home-based self-management and dementia care. These recordings contain both pre-scripted protocol and free-form conversations.

The focus of our speech recognition system is the pre-scripted conversations. Thus, we need to first extract audio recordings corresponding to patients' speech as a response to pre-scripted protocol questions. The data extraction process is designed as shown in Figure 5.

[redacted]

After extracting the data, we also need to further sanitize them, because the patient may reply with “Of course” or “Sure” as an expected “Yes” answer. We plan to parse the extracted audio clips using a series of existing, industry-leading speech recognition engines (including Google Speech-to-Text [Cloud Speech API, 2016], Nuance Dragon Professional [Nuance Dragon Professional, 2017], and Mozilla DeepSpeech [Mozilla, 2017a]). We will then compare the output from different engines for the same audio clip. Only if the results are different between engines, or [redacted] will we then mark the audio for manual transcription into text. This process can quickly generate a large training dataset with minimal human labor involved. We then compare the speech recognition results with the expected answers, and if they are the same, then these audio clips will be categorized as a correctly labeled data and will be used to train the DNN described in section 3.2.2. The rest of the data with the recognition results (either correctly recognized by speech recognition engines, or by manual transcription) will be used to train the keyword matching algorithm described in section 3.3.1.

Milestones & Success Criteria: We expect to extract and transcribe all audio clips for patients’ response to pre-scripted conversation from our existing [redacted].

Alternative Strategies: The greatest risk to this aim is the low success rate of the speech recognition engine, which may result a large amount of the audio clips needing to be transcribed manually. In that case, we will first prioritize manually transcribing the data with higher confidence scores, since our Phase II system will hand over low confidence recognition tasks to human health advocates. We will continue to parse the rest of the data in parallel with the implementation of the other specific aims and use the later transcribed data to further tune our system.

3.2.2. Phase I Specific Aim 2: Training DNN ASR Model

Overall Strategy: Using the training dataset constructed in Specific Aim 1, we will develop a Deep Neural Network (DNN) based speech recognition model specialized in recognizing the speech of elderly individuals when responding to prompting, in real-world home and eldercare environments.

Methodology & Analyses: With recent advances in machine learning for speech recognition, DNN has been shown to outperform other learning models as a noise-robust speech recognition model [Li, 2014]. Thus, we plan to train a DNN model as our speech recognition engine. To speed up our development process, we plan to train our model based on existing open source speech recognition software Mozilla DeepSpeech [Mozilla, 2017b]. Released in November 2017, this is the most advanced open source speech recognition engine, which has a word error rate of only 6.5% on LibriSpeech’s test-clean dataset, a close to human level performance [Reuben,

2017]. Our task here is to train this model using our elderly speech data recorded in noisy real-world environments, so that the model can be tailored to our specific recognition tasks.

Once the model is trained, it will be deployed to the tablet to conduct recognition tasks, as a piece of software that records the patient's voice as input, passes the input through the speech recognition model, and transfers the output to the avatar software. To achieve best performance, we plan to implement the tablet side recognition software using Android Native Development Kit (NDK) [Ableson, 2011], which is developed using a low-level C++ language and is commonly used for resource intensive tasks such as video/audio processing.

Milestones & Success Criteria: In our SBIR preparatory project, when using Google's speech-to-text engine to transcribe our data, the WER was 33%. Our goal is to train a model with lower than [redacted] when recognizing elder patients' speech, which is considered a threshold of being a useful recognition engine for comprehending speech content, based on studies testing the level of human comprehension given machine transcribed text strings [Munteanu, 2006].

Alternative Strategies: One major cause of the failed recognition in the preliminary data is due to excessive noise in the environment. If our trained model resulted in a high WER, we will consider applying noise canceling solutions using both software and hardware, including adopting a more powerful noise canceling audio codec or attaching an external microphone to the user-facing device.

3.3. Phase II Research Plan

In Phase II, we will combine software modules developed in Phase I with our human-in-the-loop system design. To ensure that our overall system performance does not degrade by introducing the ASR component, in cases where the environment is too noisy or the patient response diverges beyond the speech recognition engine's capability, we will develop a dispatching system that assigns a human health advocate to the pre-scripted conversation. The health advocates will be briefed with previous conversation logs to be prepared to pick up the conversation immediately. We will also conduct a 2-year human subjects research study (not a clinical trial) to hone our system into the best in-class ASR engine using abundant conversational data with mild-moderate AD patients in real-world scenarios, which can be used to enable other SAR solutions for this population.

3.3.1. Phase II Specific Aim 1: Keyword Matching NLP Algorithm

Overall Strategy: Our prior work shows that our patients often utter free-form responses even when the expected answer is as simple as "yes" or "no." Thus, we will develop a keyword matching module to comprehend semantically similar phrases, so that patients can interact with the system more naturally.

Methodology & Analyses: Over 90% of our existing pre-scripted protocols are yes/no questions, which work better for dementia patients who have trouble responding to open ended questions. Thus, at this stage of study, we will mainly focus on matching the speech recognition engine's output (in the form of text strings) into a "yes" or "no" answer. In natural language processing (NLP) research, this is equivalent to affirmative/negative intent parsing [Mukherjee, 2014], which has been studied and implemented in existing NLP APIs including LUIS.ai (by Microsoft), Wit.ai (by Facebook), Api.ai (by Google) and Watson (by IBM). There are also open source solutions such as NLTK [Natural Language Toolkit, 2017]. We will import the open source solution into our software running on the patient-facing device. According to our preparatory project, by having a human read the ASR recognized text, over 90% of the unexpected answers' intent can be successfully recognized. The ones that humans fail to recognize are cases where the patient deviates the topic completely away from the question, which in the short term, will result in a dispatch to a human health advocate as described in Section 3.3.2. In the long term, as our NLP algorithm proves itself to be robust enough, upon detecting a topic deviation, the system can [redacted]

Milestones & Success Criteria: We aim to reach intent parsing success rate of 90%, similar to human effort. We will feed our training dataset into the software to conduct the intent recognition task and measure the success rate.

Alternative Strategies: If our software cannot meet the goal, we will consider introducing third party NLP engines which have been used with success rate over 90% in general commercial/public use, although their success rate is likely to be poorer than advertised given our more challenging patient population.

3.3.2. Phase II Specific Aim 2: Human-in-the-Loop Implementation

[redacted]

Overall Strategy: To handle particularly challenging speech recognition and NLP tasks, especially when interacting with AD patients with neurocognitive and speech impairments, we will develop a human/AI hybrid system that dispatches low-confidence machine recognition tasks to be handled by our human staff. This system will also enable challenging machine recognition tasks to be manually labeled by our staff, enabling continuous DNN model tuning.

Methodology & Analyses: In our proposed system (Figure 6), the recognition tasks will be dispatched to human health advocates in two cases: 1) the speech recognition confidence score is low; or 2) the speech recognition confidence score is high, but the tablet cannot decide the affirmative/negative intent of the recognized text.

In the first case, the tablet-side software needs to decide when to dispatch the conversation. Similar problems have been studied in call center settings [Baker, 2003], where speech recognition software was applied to convert the customer's speech into text, and when the recognition confidence is low, the call is dispatched to a human call center staff member. Further studies showed that using a multi-threshold confidence score can further improve the ASR performance [Chang, 2010]: various confidence scores are drawn based on the length of sentences to be recognized, the gender of the speaker, and so on. The idea behind multi-threshold confidence scores is to add an extra layer of the ASR system to further customize it under finer-grain datasets. In our system, the recognition tasks are limited to short sentences because most of our pre-scripted protocols expect patients to give simple answers such as "Yes" or "No", however, unlike the call center settings where a caller's identity is unknown before the call starts, our avatars interact with patients who are pre-registered in our system and who we develop extensive knowledge about. Thus, in our case, we have the capability to develop a more advanced system that generates a threshold for each patient. We believe this fine-grained threshold can further improve system effectiveness. Thus, we will first develop a per-person threshold using methods suggested in prior work [Williams, 1999], and then [redacted].

Similar techniques can be applied to the second case, in which the NLP module cannot decide the speech intent.

We will implement software that streams the voice recording to the server and [redacted]. The health advocate will then select the proper branch [redacted] Thus, the avatar will be able to seamlessly continue the conversation under human control. Meanwhile, the system will store the branching condition selected by the health advocate, together with the uploaded audio clip. This pair of data will be used as manually labeled data to further train the ASR model.

Milestones & Success Criteria: In our SBIR preparatory project, when setting a unified confidence score of 0.9 and using an off-the-shelf speech recognition model to recognize patient's answers, the system success rate was 60%, meaning 60% of the pre-scripted protocol work load can be handed-over to our proposed automation system. Here, the workload is defined to be the number of sentences the health advocates need to send out for the avatar to speak out in an avatar-patient interaction. In this proposed project, we aim to further improve this number from 60% to be [redacted] (estimated based on the amount of improvement of our specially built speech recognition model). In this way, [redacted] of the total workload that our company performs currently using humans can potentially be taken over by software. Note that while [redacted] human workload is already very significant [redacted], other use cases such as a SAR that is intended only to provide health-related coaching, may [redacted].

Alternative Strategies: According to our above analysis, if we do not see improvement using our own speech recognition model, by switching to an off-the-shelf model, we can still achieve an automation rate of 60% for our pre-scripted conversation.

3.3.3. Phase II Specific Aim 3: Additional Model Training & Automation Validation

Overall Strategy: In order to bolster our new DNN-based ASR model with enough training data to create the world's best affirmative/negative intent parsing engine for real-world use with persons with mild-moderate AD, and to validate the engine's real-world ability to automate a substantial portion of our avatar interactions through the system developed in Phase I, thereby demonstrating commercial value for improving the scalability and gross margins of care.coach, as well as for serving as an engine that we can license to enable other socially assistive robots for persons with AD, we will need to collect additional data through a human subjects research study (not a clinical trial). The following protocols are pending IRB approval through Regenstrief Institute (FWA00003345), the research organization of Indiana University. Per the NIH single IRB policy, the care.coach IRB (FWA00025961) will submit to the authority of the Regenstrief IRB.

Methodology & Analyses: Per deep learning best practices, a supervised deep learning model is likely to achieve acceptable performance with about 5,000 labeled examples per category [Goodfellow, 2016]. In this proposed project, we will focus on training our model to recognize affirmative/negative intent (equivalent to verbal "yes" or "no" responses), meaning we will have two primary categories. Historically, with naturally phrased prompts from the avatar, we have observed a skew toward affirmative intents, accounting for about [redacted] of the total patient responses. Thus, without compromising the natural phrasing the avatar prompts, our training efficacy will be limited by the [redacted] of patient responses that have negative intent. Further accounting for a cross validation (to tune model parameters) and test (to measure model effectiveness) data set, and the expectation of requiring an order of magnitude more data to truly develop the best in-class ASR, we set a goal of [redacted] total labeled samples. With our existing avatar system currently deployed to elderly patients living at home, each patient answers an average of 7 pre-scripted questions per day, or about 2,500 per year per patient. This average represents our ability to balance between executing as many protocols as possible per day, and the need to avoid tiring out or frustrating our patients with excessive questions and requests. Therefore, we will achieve our goal of [redacted] labelled samples by collecting about [redacted] patient-years of data.

Dr. Malaz Boustani (see biosketch) through Indiana University and Eskenazi Health has access to over 3,000 of AD patients who live at home and in nursing facilities and are supported by his team of about 30 care coordinators who are in turn supported by nurses and other clinicians. Our official research site partner is Dr. Boustani's research organization, the Regenstrief Institute (affiliated with both Indiana University and Eskenazi health) which has in similar research projects been able to recruit study participants at a rate of 20 patients per month with two dedicated, full-time research assistants supported by a research manager and liaising with the larger care coordination team. Assuming a linear study enrollment ramp up period at this rate of 20 patients/month beginning at the start of the proposed SBIR Phase II, followed by a steady enrolled population until the end of Phase II two years later, we solve the system of equations that results from this model, calculating that to obtain 200 patient-years of data, we must reach an idealized steady-state enrolled population of 113 over a ramp-up period of 5.7 months, assuming no dropout. Based on experience with such complex, elderly patient populations, we expect a dropout rate of [redacted] Therefore, for the purposes of human subjects research planning and budgeting, we will plan for a peak of 200 patients enrolled into the study after a ramp-up period of 10 months.

Study participants will be selected for having mild-moderate stage AD upon study enrollment, and will undergo informed consent or informed assent with a legal representative. Research assistants (via Regenstrief subaward, liaising with the Eskenazi Health AD care coordination team) will work with the investigators to enroll each participant in suitable protocols, e.g. checking on medications, encouraging exercise, etc., as would ordinarily be done if the patient were enrolled through a care.coach healthcare provider customer. The primary purpose of doing this, however, is not to measure a particular clinical outcome (which would be challenging to measure given the diversity of the AD population), but rather to ensure that the conversational data we are gathering reflects real-world usage applicable to the commercial and healthcare goals of care.coach and other AD-focused SAR technology developers. Research assistants will securely report to care.coach any medical diagnoses that may be related to cognition and speech, as well as cognitive assessment scores as performed by Eskanazi Health every 3 months, so that these parameters can be incorporated into our proposed ASR and individualized multi-threshold system for determining ASR and NLP confidence. Please refer to the additional human subjects attachment for details on study protocols and protections for research subjects.

Milestones & Success Criteria: To demonstrate the SAR technical efficacy, we aim to achieve [redacted] automation of our avatar conversations, based on the success criteria of Phase II Specific Aim 2, contingent on no overall decrease in product usability and patient satisfaction as assessed by Regenstrief through follow-up home visits with each study participant each 6 months after initial enrollment. Evaluation and continuous refinement will commence in the second year of Phase II, after the human-in-the-loop system implementation is complete and new training data collected in the first year of Phase II are incorporated.

Alternative Strategies: Our system is designed to continuously collect data and tune the ASR and NLP systems as the study progresses. After a few iterations, the system should have gradually improving automation capability even if it takes longer than expected to achieve the success criteria.

3.4. Timeline

Specific Aims	***Phase 1***		***Phase 2 – Year 1***				***Phase 2 – Year 2***			
Quarter (3 months each):	*1Q*	*2Q*	*1Q*	*2Q*	*3Q*	*4Q*	*1Q*	*2Q*	*3Q*	*4Q*
Phase I Aim 1: Building a Training Data Set										
Phase I Aim 2: Training DNN ASR Model										
Phase II Aim 1: Keyword Matching NLP Algorithm										
Phase II Aim 2: Human-in-the-Loop Implementation										
Phase II Aim 3: Additional Model Training & Real-World Automation Validation										

STATEMENT OF WORK

Indiana University Principal Investigator: *Malaz A. Boustani, MD, MPH*

Grant Title: *Development of Socially-Assistive Robots (SARs) to Engage Persons with Alzheimer's Disease*

The Regenstrief Institute is an internationally respected informatics and healthcare research organization, recognized for its role in improving quality of care, increasing efficiency of healthcare delivery, preventing medical errors and enhancing patient safety. Established by philanthropist Sam Regenstrief on the Indiana University - Purdue University Indianapolis campus in 1969, the Institute is a 501(c)(3) organization closely associated with the Indiana University School of Medicine and the Health and Hospital Corporation of Marion County, Indiana's Eskenazi Health. Regenstrief's mission is *"Connecting and Innovating for Better Health"* and our values, *"Discovery, Impact, People and Community'.*

Regenstrief is involved in this project for its capacity to design and conduct studies in clinical research and for its capacity to securely manage and analyze research data. For the *Development of Socially-Assistive Robots (SARs) to Engage Persons with Alzheimer's Disease* project, the research staff of the Regenstrief Institute will manage all operational aspects of project implementation, including IRB approval, participant enrollment, and administration of participant incentives. Regenstrief staff will be responsible for interacting directly with subjects for study procedures, including the provision of patient incentives for participation. Gift card purchase and distribution is located **in** the Regenstrief Institute subcontract because the personnel completing these tasks are Regenstrief Institute employees.

The work to be conducted by Regenstrief Institute research support staff will be under the direction of [redacted]n her role as an Assistant Director, Operations of the Indiana University Center for Aging Research[redacted] is responsible for operational management and the translation of strategic plans into operational plans, policies, and procedures. The position develops, manages, and continuously improves Center

administration and project management functions. The position is also the chief liaison to the administration of the Regenstrief Institute, Indiana University schools, departments and centers, and other external stakeholders.

COMMERCIALIZATION PLAN

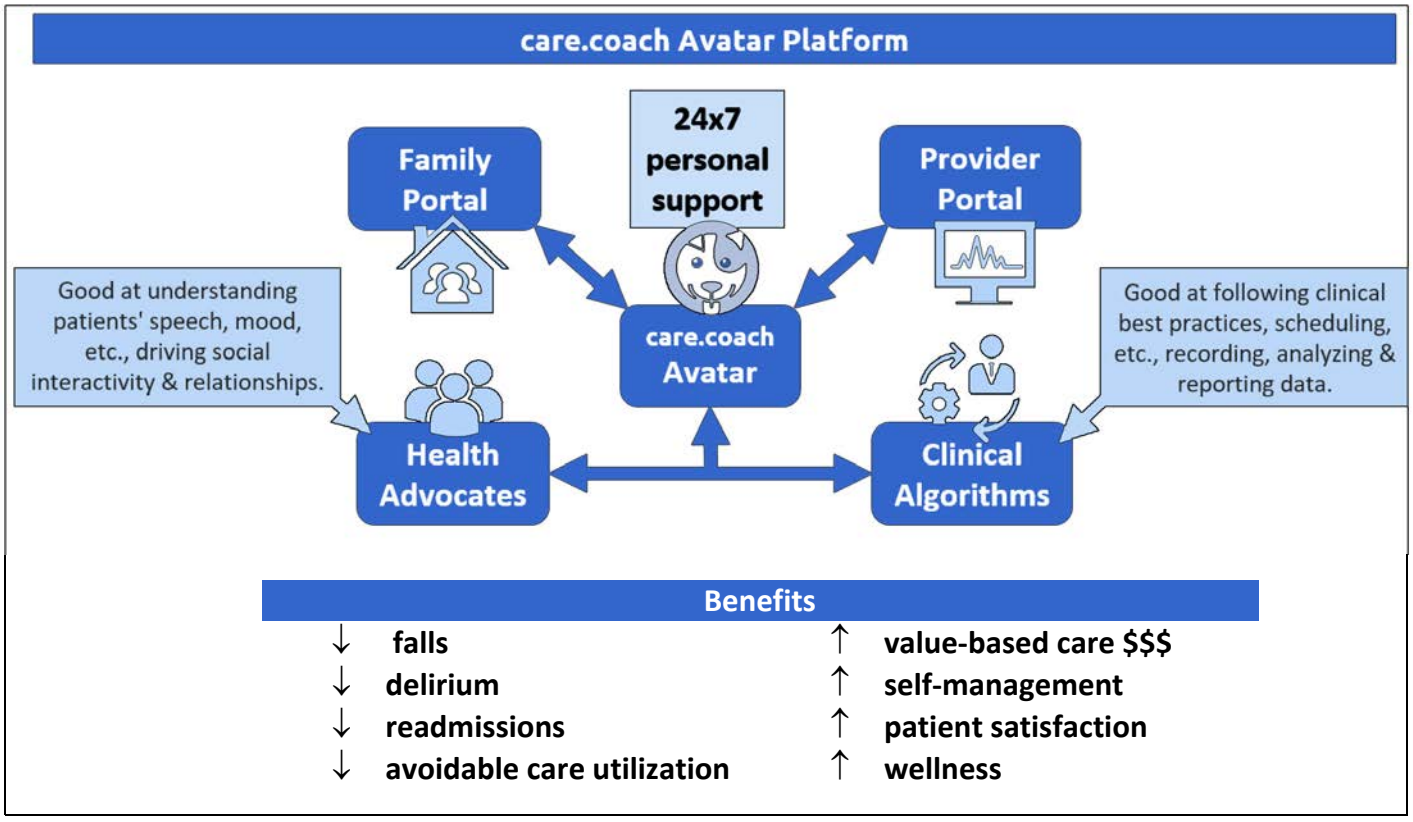
A. Value of the SBIR Project, Expected Outcomes, and Impact

1. Project and Objectives

Artificial intelligence (AI) has long been challenged by the speech of elderly persons, and especially persons with dementia, due to age-related voice tremors, hesitations, imprecise production of consonants, increased variability of fundamental frequency, and other barriers. Unlike existing approaches to socially assistive robots (SARs) relying purely on limited AI for conversation, care.coach™ has been commercializing a SAR-like avatar that converses with elderly and AD patients through truly natural speech, powered by a 24x7 team of trained human staff. The unique data sets that our solution enables us to gather at commercial scale will be leveraged in this SBIR project to develop an automatic speech recognition (ASR) and natural language processing (NLP) engine that is best-in-class for AD applications, improving the commercial scalability of our avatars by reducing our dependence on human staff, while serving as a new AI platform for enabling the next generation of AD-focused, conversational SARs.

2. Description of Platform

care.coach™ is developing a care platform that provides 24x7 proactive patient support in a more effective and lower cost way than any previously available solution. A summary of our platform is shown in the below diagram:



Our patient-facing interface appears as a virtual animal avatar on a touch-screen device. Patients interact with the avatar by speaking with it or touching it. This interface allows even complex elders who have functional impairments to be engaged effectively and in a joyful way, regardless of ability or technical inclination.

Our avatars are controlled by a remote team of “health advocates” who are background checked, psychometrically screened, and employed by care.coach™. Using our proprietary online interface, each health advocate can monitor [redacted] sequentially [redacted] through audio/visual feeds from each

patient's avatar device, and communicate with each patient by sending text commands spoken by the avatar's voice. Health advocates contribute to the system their human abilities for natural language processing and compassionate conversational responses to help each avatar build a personal relationship with its patient. While health advocates are not clinicians, they have a minimum set of certifications such as [redacted] and more.

Additionally, their abilities are augmented through a software-driven expert system embedded into their work interface, which guides them through evidence-based clinical protocols to mitigate falls and delirium, for example by executing cognitive exercises, re-orientation, and toileting checks, and alerting the nurse station of any issues requiring action.

We have also built both a Family Portal and a [redacted]l to take information from and provide feedback to both informal and formal care providers. Family members and other informal members of the care team can access the Family Portal online, 24x7, to add family content such as photos, music and family voice recordings, and attach notes to each piece of content so that our health advocates can engage our patients in reminiscence therapy, conversations about family, and more. Family members also benefit from the peace of mind of care journal entries recorded by our health advocates, documenting the engagement and supervision that care.coach provides. [redacted]

Moreover, our entire platform is HIPAA-compliant and integrates acceptably into hospital and health plan systems, as evidenced by our successful completion of information security screenings at several hospitals, health systems, and health plans across the country.

These components of our platform are illustrated below:

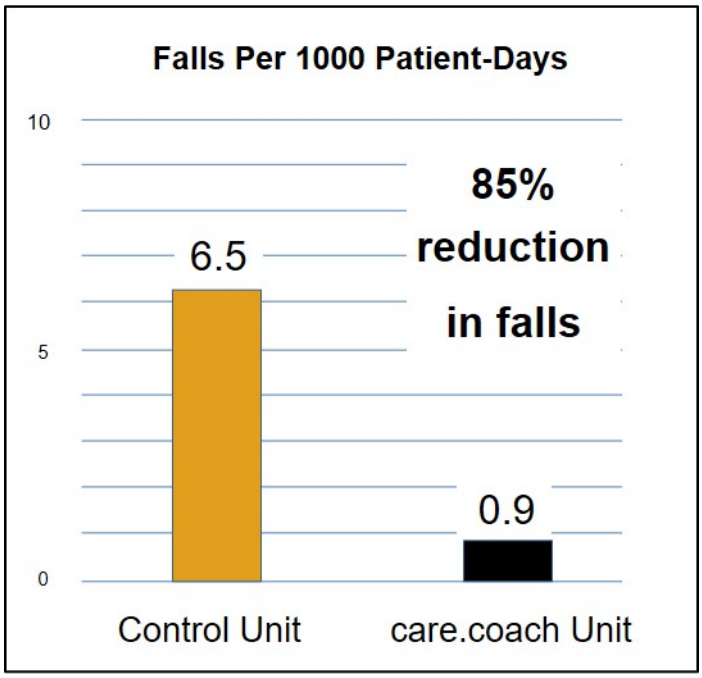
3. Clinical Need

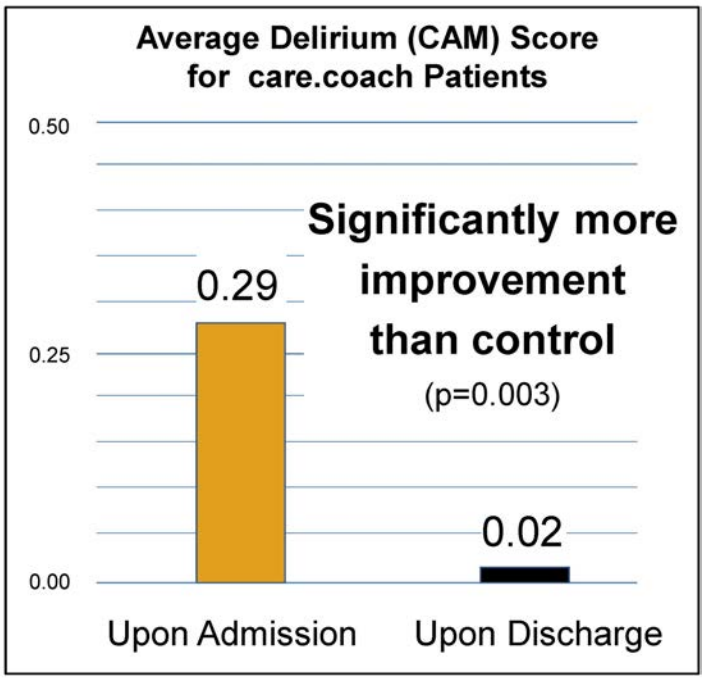
1 in 3 seniors in the United States dies with dementia, of which Alzheimer's disease (AD) is the most common form. AD patients suffer from decreased ability to meaningfully communicate and interact, which causes significant stress and burden for both professional caregivers and family members. Socially assistive robots (SARs) have been designed to promote therapeutic interaction and communication. Unfortunately, artificial intelligence (AI) has long been challenged by the speech of elderly persons, who exhibit age-related voice tremors, hesitations, imprecise production of consonants, increased variability of fundamental frequency, and other barriers that can be exacerbated by the neurological changes associated with AD, further complicated by common environmental noises such as the ceiling fan, television, etc. Because of the resulting poor real-world speech and language understanding by available SAR technologies, scarce human caregivers are often required to guide AD patients through SAR interactions, limiting SARs to small deployments, mostly as part of research studies.

4. Commercial Impact

Inpatient Care

Age and cognitive impairment are major risk factors for both falls and delirium in the hospital. In a clinical study conducted in 2016 by Pace University at Jamaica Hospital Medical Center with 95 elderly inpatients, the intervention unit which deployed prototype care.coach™ avatars at the bedside of high-risk patients showed an unprecedented 70-85% reduction in rate of falls. Compared to the national average fall rate of 3.56 falls per 1000 patient-days, the intervention unit showed a 3-month fall rate of only 0.9 falls per 1000-patient days. Intervention patients also showed significant reduction in delirium and loneliness, as well as compelling examples of restraint avoidance. The key findings are summarized below:





Because these results put the care.coach™ platform in a rare class of technology-enabled solutions with the potential to substitute for patient sitters (a [redacted]/bed/month solution), we believe that we have the potential to drive enormous commercial impact. Below is an example of annualized return-on-investment (ROI) estimator for a single hospital unit, which we embed into our pilot sales proposals for hospitals (numbers indicated as "actual" were obtained from an actual sales prospect of care.coach):

As illustrated by the above ROI estimator for one hospital unit, our commercial impact is large for any typical hospital. Most hospitals have multiple units that would benefit similarly, resulting in expected total savings potentially in excess of [redacted]/yr when other benefits are factored in. For simplicity, the cost savings of delirium mitigation that doesn't directly result in falls mitigation is excluded from the estimate, because the increase in length of stay by 7.78 days for the average case of incident delirium has a more complex negative impact on revenue by reducing throughput. Anecdotally, we have also found that the litigation cost of falls is often in excess of the treatment costs that these estimates are limited to. There are also more mathematically complex financial benefits resulting from the impact of falls on quality metrics used by CMS for calculating value-based reimbursement amounts.

Alzheimer's Care in the Community and Post-discharge from Hospitals

CMS financially penalizes hospitals for avoidable readmissions, so hospitals are motivated to invest in solutions to keep discharged patients from coming back. In addition to helping with inpatient care, our avatars have also shown strong potential to help reduce readmission rates. A post-discharge quality improvement pilot using care.coach avatars with 6 Native American heart failure and diabetes patients at Sanford Chamberlain Medical Center in South Dakota also showed strong patient engagement and examples of readmission avoidance due to the avatar support, as described in the following slides:

Case Study: Sanford Chamberlain

Post-acute, hospital readmission prevention

[redacted]

Non-compliant rural Native American population with heart failure and diabetes

<3 months from initial contact to contract, deployment & ROI from prevented readmission

[redacted]

Enhanced Patient Experience

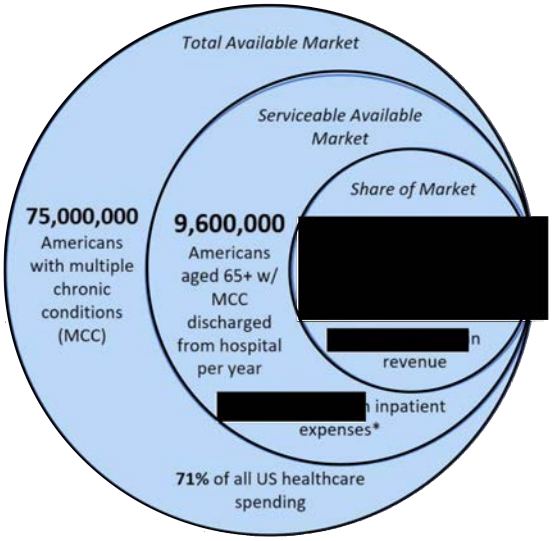
De-identified patient data shown

Health Advocate Journal Entry

I woke up and saw PATIENT. I greeted her good morning. She was taking her medications. I asked her a few questions and she was able to answer them. She said she slept well last night. **She told me she feels like quitting the cardiac rehab program but that she doesn't want them to take me away from her.** I encouraged her to continue the program and that I will be with her to support her. She said thank you. She said it was hard to do everything on her own, like cooking and preparing her meals. I agreed with her it was difficult but we will get through it in the end.

Psychosocial support and patient relationship from care.coach enables improved adherence and clinical outcomes.

Four years out from the SBIR Phase I award date, we expect based on our sales projections to have about [redacted], serving about [redacted], and resulting in almost [redacted] in annually recurring revenue, allowing profitable continued operation. We envision that most of our hospitals at this stage will be using [redacted] on an inpatient basis, and many will have also grown their utilization of our service to include up to 40 patients recently discharged home, where we will coach each patient to better self-manage their individual risk factors and mitigate risk of readmission. Six years out from the SBIR Phase I award date, we expect to have [redacted] generating [redacted] in annually recurring revenues, and representing what we consider to be our medium-term "share of market" in our market size projections. Our share of market will increase if we raise additional venture capital in excess of our current estimates, or if we successfully develop new product lines or new markets addressing our target patient population:



5. Societal and Scientific Impact

According to the Association for Psychological Science, "loneliness contributes to, and accelerates, age-related decreases in physiological resilience through its influences on health behaviors, stress exposure, psychological and physiological stress responses, and restorative processes."

Unfortunately, many elderly patients do not have supportive family caregivers with high availability, and the high cost of labor in developed countries has not allowed the healthcare system itself to adequately address the psychosocial, human side of wellness and resilience. Most technology solutions so far have failed to engage such at-risk populations as elders who lack affinity for technology.

The care.coach™ platform has already shown its ability to mitigate loneliness, including in the hospital inpatient environment, and our success in the market and eventual growth into post-discharge and community-based care will address this vital societal need.

Scientifically, many researchers have studied and confirmed the potential efficacy of human driven digital avatars in healthcare, but have been unsuccessful in scaling such innovation commercially. By being the first to scale a human/software hybrid avatar in the market, and through our academic partnerships, we will significantly advance the scientific community's understanding of human relationships with virtual agents, behavior change models, and other domains that will benefit from our unique ability to aggregate at scale large amounts of observations and conversational data, ranging from structured to free-form, with elderly or otherwise high-risk patient populations.

From a more general scientific perspective of developing "strong" artificial intelligence that is truly indistinguishable from human intelligence in conversation, care.coach will also be an enabler by providing at scale the kind of "open domain" conversational data that would otherwise be incredibly expensive to generate and record, but is necessary for training any such artificial intelligence.

6. Role of SBIR/STTR funding in business strategy

The ASR/NLP and AI/human dispatching system that we develop in this proposed SBIR project will enable a [redacted] and improving both ease of product scalability and the appeal of our company to financial investors. The ability to license our AD-specialized conversational engine to other companies seeking to develop conversational interfaces and SARs for people with AD may also create a substantial new revenue opportunity for us.

Moreover, the “Alzheimer’s care industry” is dispersed across the continuum of care, as dementia was widespread implications for the care of hospitalized elders, readmission rates, long term care, caregiving burden, etc. Many of our sales prospects have mentioned to us in the sales process their struggles with their cognitively/memory impaired population, both in the hospital and in the community, across a range of business models and clinical scenarios. This SBIR project would enable us to establish stronger evidence of our avatars’ abilities to support patients with dementia, which will potentially enable additional sales to many healthcare providers struggling with this population.

In general, we seek to leverage SBIR funding to raise venture capital to grow and continue to innovate faster in the market. Investors that we have spoken with have suggested seeking SBIR funding in order to leverage their prospective equity investment and to take our company to a stage that is more opportune for raising venture capital (additional technological sophistication, clinical validation, and revenue traction). Please refer to Dr. [redacted] support letter included with this proposal. From the perspective of NIH, given that we aim to raise approximately [redacted] in funding in addition to the amount requested in this proposal, the funds from NIH will be leveraged [redacted] in terms of marking a positive impact on the US healthcare system.

B. Company

1. Description and Corporate Objectives

The mission of care.coach is to compassionately support each individual in their care journey, and to help providers to achieve the Triple Aim of healthcare with their most complex patients across the care continuum: (1) improve the patient experience of care, (2) improve the health of populations, and (3) reduce cost of care.

2. History, Team and Core Competencies

Victor Wang, CEO/Co-Founder: MIT MS (Human-machine interaction). Canadian army, medical robotics, etc.

[redacted]

Brittany Wang, Program Manager: MA Gerontology, RCFE license. Sunrise, Agesong, Wix.com.

[redacted]

[redacted]

History: Victor came up with the idea for care.coach based on his family experience with his grandmother in Taiwan who lived by herself and became very lonely and depressed. She was eventually diagnosed with dementia, and like 42 million other family caregivers in the US, Victor's mother sacrificed a lot to care for her. Victor's wife and care.coach Program Manager, Brittany Wang, is also a Gerontologist and former personal caregiver, and brings an understanding that much of the problem in modern healthcare comes from the limited attention given to the psychosocial needs of typically older patients, who often must endure disorienting hospital stays and transitions of care, manage multiple chronic conditions and self-care plans, and often with sparse family/social support and encouragement. [redacted]

Additional Co-Founder Info:

Victor graduated as Wesbrook Scholar from the University of British Columbia and worked in telemarketing, environmental research, aerospace manufacturing, particle physics, oil sands, medical robotics, and the military, before earning his Master of Science at MIT, where his research involved novel characterizations of human-machine interaction for NASA's telerobotics program, as well as a clinical study at Brigham & Women's Hospital. He's presented at the AARP Expo, Connected Health Symposium, CES Silvers Summit, TEDMED, US Senate Healthy Aging Forum, Aging in America, SOCAP Social Capital Conference, Health 2.0 Europe (via a care.coach avatar), and many other local, national, and international events.

[redacted]

3. Previous Federal and non-Federal funding

We have not yet directly received any federal funding. In terms of equity-based investments, we have received [redacted] in private [redacted] funding, including well-known healthcare investor [redacted] (also an investor or board member in [redacted], etc), and [redacted] from [redacted]. We have also received [redacted] in non-dilutive grant funding from [redacted], the non-profit arm of the world's second largest re-insurance company.While we were also the co-winners of a [redacted] grant to execute a clinical study at Jamaica Hospital Medical Center, [redacted]

4. Long-Term Vision for the Company

As described previously, we seek to grow from inpatient care into post-discharge and community-based care as well, growing our annualized recurring revenues to at least [redacted] within [redacted] years of the SBIR Phase I award date. [redacted] we aim to reach a market capitalization in excess of [redacted], with a broad market reach spanning providers (health systems, senior living community, home care providers, etc), payers (PACE health plans, Medicare Advantage Special Needs Plans, etc), and patients (direct to consumer/family caregiver).

Ultimately, if we successfully execute on our long-term technology roadmap involving increased levels of automation and artificial intelligence, our terminal enterprise value is essentially unlimited, as we will expand into adjacent clinical domains such as pediatrics and oncology. As our marginal costs decrease, and as we add capabilities such as control over robots capable of guiding patients through the hospital, or physically helping a patient to transfer out of bed, our applications will become limitless.

5. Overall Growth Strategy and Hiring Plans

To grow to [redacted] within [redacted] years of the Phase I start date, in conjunction with additional equity funding through venture capital, we seek to hire as follows:

[redacted], so we do not foresee any difficulty in finding qualified health advocates, [redacted]

C. Market, Customer, and Competition

1. Target Market

Our primary target customers are risk-bearing hospitals and health systems, [redacted]. These organizations are incentivized not just to improve hospital inpatient care and reduce inpatient cost of care, but also to provide adequate support post-discharge for higher-risk patients, because they are liable for other costs of care such as readmission caused by failure to adhere to medications or proper wound care, additional physical therapy due to poor engagement in self-directed exercises, or unnecessary emergency department visits caused by loneliness/isolation-related anxiety.

We have talked with [redacted], and they are very excited by our multi-faceted, person-centered and person-driven approach to driving cross-continuum outcomes. Sometimes they are more interested in coaching patients at home for multiple chronic conditions, and sometimes they are more interested in the inpatient use case, depending on their organizational priorities and existing payment structures, but they all recognize the uniqueness of the care.coach solution and the power of being able to expand any initial deployment to be truly cross-continuum, bringing together their disparate service lines in the face of value-based healthcare reform and organizational consolidation.

Various individuals typically need to contribute to the purchasing decision, but we would consider the primary top-level decision maker to be a [redacted]

2. Customer Profile

We currently seek to target risk-bearing hospitals and hospital-based health systems with a focus on reducing delirium or readmissions, which are both impacted by cognitive and memory deficits.

Secondarily, we also seek to sell into the payer market, with a focus on PACE (Program for All-Inclusive Care for the Elderly) health plans and similar Medicare Advantage Plans (particularly, [redacted]. All of these organizations struggle with their members living with dementia.

3. Competitive Advantages

For a high-risk, elderly patient population, we do not believe there is any competitor that can match care.coach in value vs. ease of adoption. This is detailed in the Competitive Landscape section.

4. Commercialization Hurdles

A primary hurdle to commercialization is the level of clinical validation that many health systems require prior to considering a large sales contract for a clinically oriented intervention. The funding provided by the SBIR program would enable us to advance our product and develop the robust validation necessary to rapidly sell our solution into health systems across the nation.

5. Partners

Our academic and research partners include [redacted]. In addition to collaborations on technology development and grant applications, several of our partners have already deployed our avatars with patients and published papers about our work together. Please review the biosketches included in this SBIR application for published work regarding our academic collaborations.

6. Competitive Landscape

Our primary competitor in the inpatient domain is the incumbent solution of [redacted] it is a purely passive monitoring solution, and therefore not as effective as the care.coach™ platform which proactively engages and supports patients to receive assistance when needed, and to mitigate delirium.

There are also digital avatar-based solutions such as [redacted] that can support patients post-discharge or in the community. However, as they rely on the limited capabilities of software intelligence, they are not capable of engaging elderly patients the same way care.coach™ can, especially when it comes to patients with AD or who otherwise have cognitive or speech impairments. It is possible that with vast improvements in technology, purely software-driven solutions including avatars and robots will catch up to care.coach's current capabilities, but by then, the rich machine learning training set that care.coach has logged using real human intelligence controlling the avatars will enable us to leverage such advancements in artificial intelligence better than other companies, as described in this SBIR proposal.

Our competitive matrix, including several potential competitors for in-home or post-discharge use, is shown below:

7. Marketing/Licensing/Sales Strategy

We currently perform direct sales to hospitals through introductions by advisors, sales consultants, and conferences. Please refer to the Marketing Plan section for additional details.

D. Intellectual Property (IP) Protection Strategy

[redacted] We aim to continue to produce patents as they are appropriate to the defense of our IP. However, most of our IP is embodied by our software code, programmed clinical and workflow protocols, and internal processes, which together form a body of trade secrets proprietary to care.coach™.

E. Financing and Revenue Plan

1. Financing Strategy

In addition to the Phase I and Phase II SBIR funding requested in this proposal, we seek to raise additional venture capital to grow more quickly than we could organically. This will be structured as a seed/venture round of [redacted]

2. Pro-forma

The following figures are shown in thousands of dollars, and are estimated at each period end date, starting from the disbursement of the Phase I award.

	1HY1	2HY1	1HY2	2HY2	1HY3	2HY3	1HY4	2HY4
Revenue	[redacted]							
SBIR								
Investment								
Sales Revenue								
Expenses								
COGS								
Operating Payroll								
Other OpEx								

F. Production and Marketing Plan

1. Production

We provide all hardware required for our clients to utilize our service as part of our [redacted] fee. Due to the relatively low hardware production rate compared to the high rate of engineering design improvements (for example, [redacted] we currently manufacture all hardware in-house, at a cost inclusive of labor of approximately [redacted] per unit. [redacted].

2. Marketing

Pricing

We currently charge [redacted]

Promotion

We are widely considered to be an innovative and novel solution, and as such we are afforded some preferential promotion opportunities. For example, Victor Wang was specially invited to present/attend at each of the following events last year:

- Presented at Hospital Elder Life Program Conference (April 6-7 in Pittsburgh)
- Attended AARP Innovation@50+ (April 12-13 in Mountain View)
- Attended d.health Summit (May 10 in NYC)
- Presented at HxRefactored (June 20-21 in Boston)
- Presented at IAGG World Congress (July 23-27 in San Francisco)
- Presented at Health2.0 (October 1-4 in San Francisco)
- Moderated Panel at SOCAP Social Capital Markets (October 10-13 in San Francisco)
- Presented at National PACE Association Conference (October 15-18 in Boston)
- Chaired National Falls Prevention Conference (November 13-15 in Philadelphia)

Additionally, our academic partners presented at the following venues:

- Pace University presented care.coach at the Meridean Health System Geriatric Nursing Conference (June 21 in New Jersey)
- Both University of Washington and Pace University presented care.coach at the IAGG World Congress of Gerontology and Geriatrics (July 23-27 in San Francisco)

G. Revenue Stream

As described above, we already generating commercial revenues by charging on an avatar utilization basis. Below is our current pricing table:

[redacted]

April 2, 2017

To whom it may concern:

I write this letter in strong support of care.coach and its NIH grant application.

I am a PhD gerontologist and the co-founder of the Aging2.0, a global innovation network focused on the intersection of aging and technology.

I have known Victor Wang since 2012 when he presented his novel idea about avatar-enabled care at one of our Aging2.0 events in New York City. At the time, his company was called GeriJoy. Over the past 5 years, my partners and I have been impressed by the way Victor and his team have evolved their solution from a tech-enabled senior companionship service into a highly innovative, high-tech plus high-touch care coordination platform and service.

Through Aging2.0, my team and I have met and evaluated thousands of startups from around the world. Care.coach's unique combination of compassionate human support with software-driven clinical and care algorithms using an engaging, always-present avatar makes it stand out from the crowd. Specifically, care.coach (formerly GeriJoy) was selected to participate in the second cohort of our Aging2.0 Academy program. As the only accelerator program focused on aging and senior care, the Academy applicant pool is large and selection is very competitive. As a result of care.coach's participation in the Academy program, Aging2.0 has taken on a formal advisory role with the company as well.

I am confident that with the successful accomplishment of the these milestones and market/clinical validation, the company would be highly competitive and should be well positioned to raise capital to continue at a high growth rate.

To conclude, I believe that an NIH investment in care.coach would result in powerful and lasting improvement to the quality of care for our aging population, as well as significant cost savings across the US healthcare system. If you have any questions, please feel free to contact me at [redacted]

Sincerely,

[redacted]

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RESOURCE SHARING PLAN

Subject to all applicable patient safety, privacy, and security regulations and policies, as well as the proprietary nature of our trade secrets, care.coach intends to publish as much data as possible that results from this NIH funded work. Following protection of any applicable intellectual property, we will strive to publish our findings and certain non-sensitive, de-identified (per HIPAA Privacy Rule) sets of data, at minimum at the NIH National Library of Medicine's (NLM) PubMed Central (PCM), in compliance with the NIH Public Access Policy.

Compared to other small business concerns, we have a particularly clear pathway to sharing of our findings and clinical data both in academia and in the nursing industry, because the College of Health Professions at Pace University, one of our research partners, is supported by The Center of Excellence – Advancing Leadership, Partnerships, and Scholarship (ALPS). Moreover, to foster the dissemination of new, clinically beneficial technology and new clinical knowledge, and to learn from other leading researchers in the field, Pace University seeks to build a collaborative research network. As a comparatively new National Hartford Center of Gerontological Nursing Excellence, Lienhard School of Nursing will apply through the NIH/NINR P20 Exploratory Grant mechanism to become a Center for Technology to Prevent Delirium, under the leadership of [redacted] and [redacted] who are consultants on this proposed project.

Moreover, as described in the Research Strategy, care.coach intends to [redacted]

care.coach's Company Controlled Facilities and Resources

Office

care.coach's office ([redacted] is located in [redacted]. It contains computers for research and business use, a color laser printer, individual desks for each employee, white boards for discussion, and other common office furnishings and supplies.

Computer

The company has [redacted] with commercial-grade broadband Internet service. A[redacted]

Hardware Workshop

The company has a workshop for manufacturing special hardware, such as enclosures that mount the care.coach avatar tablet onto hospital beds or that stand the avatar upright on a table at home in a user-friendly way, while also preventing patients from unplugging or inadvertently disabling the device. The workshop contains the following equipment:

[redacted]

Other Resources

Board of Directors

While the CEO is the sole board director, the company has established a network of thought leaders and domain experts that support the development of care.coach service as advisors. Members of care.coach's advisory board include:

- [redacted], the past President/CEO of AARP, On Lok, and the American Geriatrics Society
- [redacted], a leading angel investor, particularly in healthcare
- [redacted], founder of the Partners HealthCare Center for Connected Health

We also have ready access to a wide range of subject matter experts and business leaders through the connections described below.

care.coach's Environment

As a member/alumni of various organization and programs, care.coach has access to a broad range of expertise, business development and fundraising connections and introductions, and talent.

care.coach is an alumnus of the Aging2.0 Academy and lifetime member of the Aging2.0 Alliance, which is a global network of leaders in senior care, including organizations such as [redacted] (the largest senior living provider in the US), [redacted] (a [redacted] private equity fund focused on aging care), and [redacted] [redacted](a leading hospital in [redacted]). We meet several times per year to discuss trends, ideate, and share best practices.

care.coach is an alumnus of [redacted] a competitive program offered to leading startup companies to help build relationships with [redacted] (one of the world's largest telecommunications providers, based in Paris) and its corporate partners. care.coach is invited to many [redacted] related events, which bring in corporate partners and investors.

care.coach is an alumnus of [redacted], the leading healthcare startup accelerator program in [redacted] It is through [redacted] that care.coach (at the time called GeriJoy) received our first angel investments. It is also through associated connections that we could build our initial academic partnerships to execute prior research with Pace University and Jamaica Hospital Medical Center.

care.coach is an alumnus of the highly competitive [redacted], through which we met many potential investors and customers who we continue to develop.

care.coach is a recipient of [redacted] funding, and is an official partner of [redacted], with the goal of increasing resilience in aging populations. [redacted] is the world's second largest re-insurance company.

Regenstrief Institute

The Regenstrief Institute is an internationally respected informatics and healthcare research organization, recognized for its role in improving quality of care, increasing efficiency of healthcare delivery, preventing medical errors and enhancing patient safety. Established by philanthropist Sam Regenstrief on the Indiana University – Purdue University Indianapolis campus in 1969, the Institute is a 501(c)(3) organization closely associated with the Indiana University School of Medicine and the Health and Hospital Corporation of Marion County, Indiana's Eskenazi Health. Regenstrief's mission is "Connecting and Innovating for Better Health" and our values are "Discovery, Impact, People and Community."

Regenstrief is involved in this project for its capacity to design and conduct studies in clinical research and for its capacity to securely manage and analyze research data. For the human subjects research component of this SBIR Phase II project, the research staff of the Regenstrief Institute will manage all operational aspects of study implementation, including IRB approval, participant enrollment, and administration of participant incentives for participation. Gift card purchase and distribution is located in the Regenstrief Institute subcontract because the personnel completing these tasks are Regenstrief Institute employees.

The work to be conducted by Regenstrief Institute research support staff will be led by Prof. Malaz Boustani as the site PI, and will be supported by the administrative direction of Bridget Fultz, in her role as Assistant Director, Operations of the Indiana University Center for Aging Research.

Eskenazi Health

For nearly 160 years, Eskenazi Health has offered high-quality, cost-effective and patient-focused health care to the residents of Marion County and Central Indiana. As one of America's largest essential health care systems, Eskenazi Health provides treatment and services to nearly 1 million outpatient visitors each year.

Partnering with the Indiana University School of Medicine, Eskenazi Health serves as the public hospital division of the Health & Hospital Corporation of Marion County. Physicians provide a comprehensive range of primary and specialty care services at the 315-bed hospital and outpatient facilities both on and off of the Eskenazi Health main campus as well as at 10 Eskenazi Health Center sites located throughout Indianapolis.

Accredited by The Joint Commission and named one of the nation's 150 best places to work by Becker's Hospital Review, Eskenazi Health's programs have received national recognition while also offering new health care opportunities to the local community. As the sponsoring hospital for Indianapolis Emergency Medical Services, the city's primary EMS provider, Eskenazi Health is also home to the first adult Level I trauma center in Indiana, the region's only adult burn center, Indiana's first community mental health center and the Eskenazi Health Center Primary Care – Center of Excellence in Women's Health, just to name a few.

Indiana University

Indiana University (IU) is a multi-campus public university system in the state of Indiana, United States. Indiana University has a combined student body of more than 110,000 students, which includes approximately 46,000 students enrolled at the Indiana University Bloomington campus and approximately 31,000 students enrolled at the Indiana University – Purdue University Indianapolis (IUPUI) campus.

According to the National Association of College and University Business Officers (NACUBO), the value of the endowment of the Indiana University and affiliated foundations in 2016 is over [redacted]. The annual budget across all campuses totals over [redacted]. The Indiana University Research and Technology Corporation (IURTC) is a not-for-profit agency that assists IU faculty and researchers in realizing the commercial potential of their discoveries. Since 1997, university clients have been responsible for more than 1,800 inventions, nearly 500 patents, and 38 start-up companies.

Just In Time Report

Report submitted on : 08/24/2018 06:37 AM

IRB Confirmation:

Human Subjects Assurance Number:

Human Subjects Education: No Human Subjects Education was provided

IACUC Confirmation: No IACUC Certification was required

For New and Renewal Applications

PHS 398 OTHER SUPPORT

KEY PERSONNEL (EMPLOYEES)

WANG, V.

ACTIVE

1R44NR017842-01 (Wang V) 5/1/2018 – 10/31/2018 [redacted]
NIH/NINR [redacted]

A Protocol-Driven, Digital Conversational Agent at the Hospital Bedside to Support Nurse Teams and to Mitigate Delirium and Falls Risk

The major goals of this SBIR Fast-Track Phase 1 project are to develop more robust clinical protocols for our human-powered avatar to help prevent delirium and falls among inpatients, and to develop electronic medical record integration in preparation for a multi-site clinical trial to measure the efficacy of the improved system.

PENDING

[redacted]

OVERLAP

None.

WANG, B.

ACTIVE

1R44NR017842-01 (Wang V) 5/1/2018 – 10/31/2018 [redacted]
NIH/NINR [redacted]

A Protocol-Driven, Digital Conversational Agent at the Hospital Bedside to Support Nurse Teams and to Mitigate Delirium and Falls Risk

The major goals of this SBIR Fast-Track Phase 1 project are to develop more robust clinical protocols for our human-powered avatar to help prevent delirium and falls among inpatients, and to develop electronic medical record integration in preparation for a multi-site clinical trial to measure the efficacy of the improved system.

PENDING

[redacted]

OVERLAP

There is possible effort overlap in the proposed SBIR project Phase II when 3.6 calendar months of effort per year are expected of Brittany Wang. If the proposed SBIR project is funded, we will obtain approval from our NINR program officer and/or Department of Defense grant officer to offload effort on 1R44NR017842-02 and/or W81XWH1810634 from Brittany Wang to a new clinical administrative manager currently in the process of joining care.coach.

KEY/PAID CONSULTANTS

[redacted]

ACTIVE

1R44NR017842-01 (Wang V) 5/1/2018 – 10/31/2018 [redacted]
NIH/NINR [redacted]

A Protocol-Driven, Digital Conversational Agent at the Hospital Bedside to Support Nurse Teams and to Mitigate Delirium and Falls Risk

The major goals of this SBIR Fast-Track Phase 1 project are to develop more robust clinical protocols for our human-powered avatar to help prevent delirium and falls among inpatients, and to develop electronic medical record integration in preparation for a multi-site clinical trial to measure the efficacy of the improved system.

PENDING

1R44NR017842-02 (Wang V) 11/1/2018 – 10/31/2020 [redacted]
NIH/NINR [redacted]

A Protocol-Driven, Digital Conversational Agent at the Hospital Bedside to Support Nurse Teams and to Mitigate Delirium and Falls Risk

The major goals of this SBIR Fast-Track Phase 2 project are to conduct a multi-site clinical trial to measure the efficacy of an improved human-powered avatar-enabled delirium and falls prevention system for hospital inpatients, and to leverage electronic medical record integration to improve automatic protocol assignment to individual patients, as well as to automatically detect delirium.

OVERLAP

None.

Phase I (6 months) Budget Justification

Senior/Key Persons:

Victor Wang (PI, [redacted]). Mr. Wang is CEO of care.coach. He has a broad background in robotics and human-machine interaction, with specific training and expertise in teleoperation, medical devices, human factors, and clinical research, including work with hospitals and IRB-approved study protocols. As an awardee or key consultant on several university- and externally-funded grants, Mr. Wang developed much of the groundwork for the proposed research by conceptualizing and implementing the techno-organizational platform required to scale a human-software hybrid avatar solution, and by establishing strong ties with healthcare providers and academia. Mr. Wang will administer the project's staffing, intellectual property protection, and budget, as well as all aspects of technology design, development and execution. As the care.coach Privacy and Information Security Officer, Mr. Wang will also ensure that all relevant institutional policies are upheld.

Brittany Wang (Co-Investigator, [redacted]). Mrs. Wang is Senior Program Manager of care.coach and has a Master's degree in Gerontology, with extensive work experience leading activities, life enrichment/engagement, and memory care programs for senior care and dementia care providers. She will advise on practical/experiential aspects of elderly speech and conversation with our avatars as required for the development and parameter tuning of the Phase I ASR engine, and will assist in the management of the human transcription process and the preparation of data.

Other Personnel:

Software Engineer, Machine Learning ([redacted]

[redacted]

Travel:

Domestic Travel: [redacted].

Other Direct Costs:

Consultant Services ([redacted]): *(Note that based on the scientific reviewer feedback, we are adding [redacted] here, and that based on NINR guidance on another award, we are moving [redacted] from Key Persons to the consultant category because she is paid as such rather than as an employee on payroll. Dr. Harati's budget comes out of the previous budget for [redacted] resulting in no net change in budget.)*

[redacted]

[redacted] @ [redacted]). [redacted] is an expert in machine learning and speech recognition, with special experience in healthcare. He will leverage his expertise to advise and manage the success of the machine learning engineering and automatic speech recognition development effort.

Transcription ([redacted]): Up to [redacted] at [redacted], to establish the training data for patient audio segments with poor recognition confidence when recognition is attempted through off-the-shelf ASR engines.

[redacted] Advisor, [redacted]

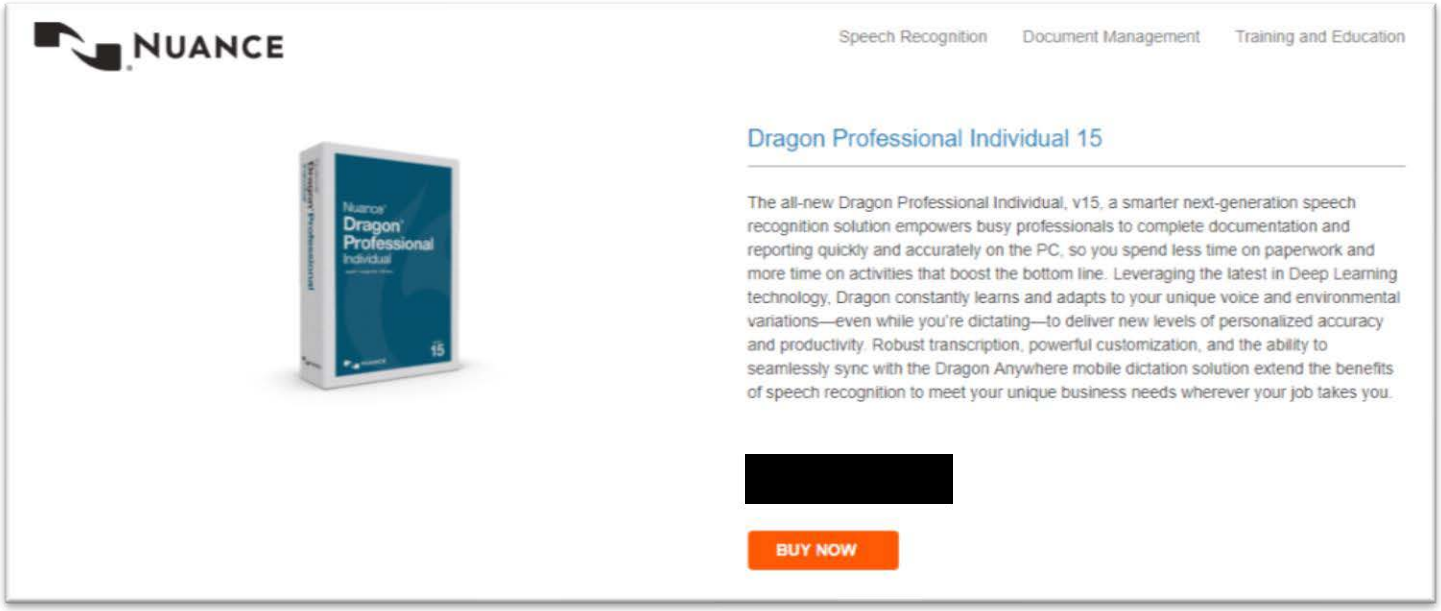
Computers ([redacted]):

[redacted] x 2 computer workstations for two new engineering hires working 100% on this SBIR project. Will be used throughout Phase II as well.

[redacted] x 2 computer workstations dedicated to running offline ASR engines to process our audio data, one for Nuance Dragon Professional (commercial), and the other for Mozilla Deep Speech (open-source). Depending on which engine is better for our use case, one of the engines may be discontinued and the associated workstation repurposed for the new software engineer hire in Phase II.

Paid ASR Software/Service [redacted]

Nuance Dragon Professional [redacted]: Software download license as shown below.



Google Cloud Speech [redacted]: Up to [redacted] minimal duration (<[redacted]) transcriptions per Google's pricing described below, with a safety factor compared to our [redacted] audio because of Google's policy of rounding duration up by increments of [redacted]

Pricing

SEND FEEDBACK

The Cloud Speech API is priced monthly based on the amount of audio successfully processed by the service, measured in increments rounded up to 15 seconds. Pricing tiers are based on the total amount of audio processed by the service per month.

Pricing Table

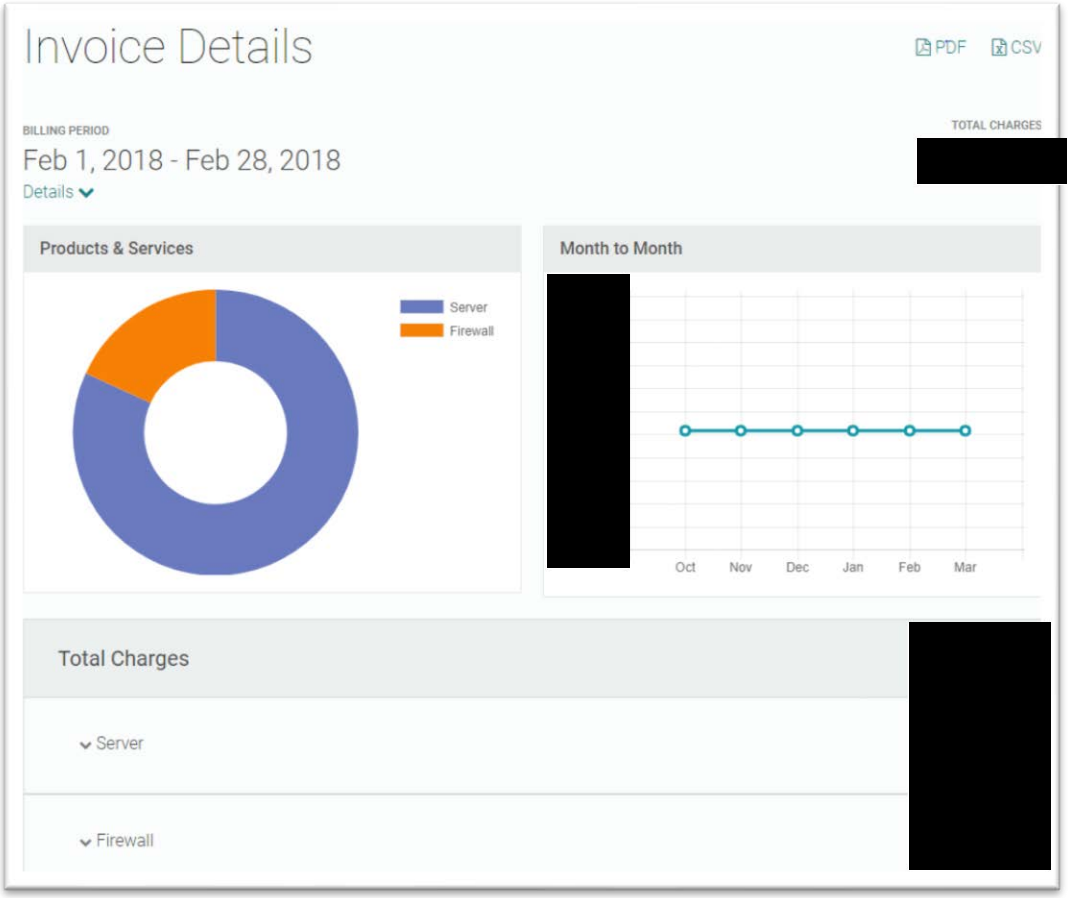
Feature	0-60 minutes	Over 60 minutes, up to 1 million minutes
Speech Recognition	Free	[redacted]

This pricing is for applications on personal systems (e.g., phones, tablets, laptops, desktops). Please contact us for approval and pricing to use the Speech API on embedded devices (e.g., cars, TVs, appliances, or speakers).

* Each request is rounded up to the nearest increment of 15 seconds. For example, if you make three separate requests, each containing 7 seconds of audio, you are billed [redacted] for 45 seconds (3 × 15 seconds) of audio. Fractions of seconds are included when rounding up to the nearest increment of 15 seconds. That is, 15.14 seconds are rounded up and billed as 30 seconds.

Server [redacted]

[redacted] bill for a capable dedicated server for [redacted] at [redacted]/month, as shown below. This relatively powerful, secure, and reliable development server will function as the heart of our technology build. It will host all of our data, internally developed software tools for data labelling and ASR engine training, and coordinate the transfer and consolidation of data between our various cloud-based, offline, and human transcription systems.



Indirect Costs:

care.coach does not yet have a negotiated indirect cost rate. The company's indirect cost rate will be 35%. Part of the indirect cost will go to rent and utility payment (please refer to the Letter of Support attachment for rent details). Additionally, care.coach is required to carry a significant amount of liability and professional insurance in order to maintain its contracts with certain healthcare providers.

Fee:

care.coach requests a 7% fee. These funds will be used to [redacted]

Phase II Year 1 Budget Justification

Senior/Key Persons:

Victor Wang (PI, [redacted]). Mr. Wang is CEO of care.coach. He has a broad background in robotics and human-machine interaction, with specific training and expertise in teleoperation, medical devices, human factors, and clinical research, including work with hospitals and IRB-approved study protocols. As an awardee or key consultant on several university- and externally-funded grants, Mr. Wang developed much of the groundwork for the proposed research by conceptualizing and implementing the techno-organizational platform required to scale a human-software hybrid avatar solution, and by establishing strong ties with healthcare providers and academia. Mr. Wang will administer the project's staffing, intellectual property protection, and budget, as well as all aspects of technology design, development and execution. As the care.coach Privacy and Information Security Officer, Mr. Wang will also ensure that all relevant institutional policies are upheld.

Brittany Wang (Co-Investigator, [redacted] Mrs. Wang is Senior Program Manager of care.coach and has a Master's degree in Gerontology, with extensive work experience leading activities, life enrichment/engagement, and memory care programs for senior care and dementia care providers. In Phase II Year 1, she will maintain the day-to-day efficacy of our system during the human subjects research by managing the health advocate team and coordinating with our care.coach technical staff and clinical/research partners on meeting product/operational/data requirements. She will also advise on the design details of the proposed ASR/NLP-human handoff interface to be incorporated into our existing health advocate interface.

Other Personnel:

Software Engineer, Machine Learning ([redacted]). This engineer in Phase II Year 1 will focus on the implementation of the keyword matching algorithms, the interface between the resulting NLP engine and the dispatch system, [redacted]

Software Engineer, Android [redacted]). This engineer will be responsible for the ongoing implementation and improvement of our ASR platform on the Android side, with focus on optimization for speed of performance. This engineer will also implement any Android app changes and avatar software improvements that are likely to become necessary as we [redacted]r.

Software Engineer, Web ([redacted]. This engineer will focus on the development of the dispatch system, and will coordinate closely with the machine learning engineer as well as with Brittany Wang on the detailed design of the user experience/interface for handoff of automated conversations to health advocates when the machine recognition confidence is too poor. [redacted].

Travel [redacted]:

Domestic Travel: [redacted].

Conferences: [redacted].

Other Direct Costs:

Materials and Supplies [redacted]: Hardware and assembly of 200 care.coach devices, at [redacted] device.

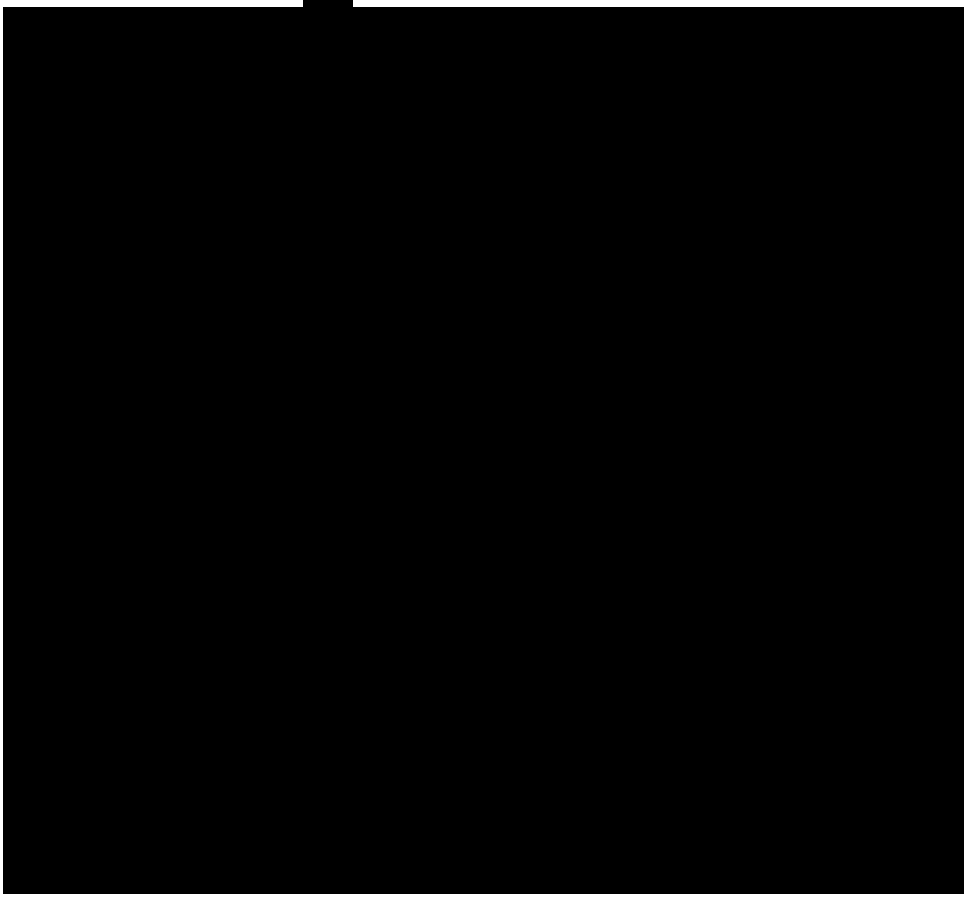
[redacted]

2. Clamp: [redacted]

[redacted]

6. Coating spray & other minor supplies (rubber, screws, glue, paper, sanitization wipes, etc: [redacted]/device

7. Production labor: [redacted]



8. Quality assurance, shipping and handling: [redacted]

Publication Costs

For a study design and interim progress paper in a research/industry journal.

Consultant Services ( ): *(Note that based on the scientific reviewer feedback, we are adding here, and that based on NINR guidance on another award, we are moving from Key Persons to the consultant category because she is paid as such rather than as an employee on payroll. budgets come out of the previous budget for resulting in no net change in budget.)*

/hr =).

@ hr =). is an expert in machine learning and speech recognition, with special experience in healthcare. He will leverage his expertise to advise and manage the success of the machine learning engineering and ASR effort.

@ /hr =). is an expert in full-stack software development, natural language processing, natural language generation, dialog management, machine learning, conversational interfaces, embodied interaction, and social robotics. He will work with to manage the success of the NLP engineering effort and of the integration with the dispatch system, as well as the design of dialog and natural language generation algorithms to maintain novelty and engagement over time.

Transcription (at /hr, to ensure that all new training data collected from Regenstrief patient-avatar conversations are incorporated into the learning model, even if all available ASR engines have poor recognition.

Prof. Malaz Boustani (Co-Investigator & Regenstrief Site PI,). Dr. Boustani is a senior implementation scientist with extensive experience in mentoring junior investigators and conducting implementation research with a main focus on developing tools, processes, and strategies to rapidly implement evidence-based and cost-effective health care solutions in the real world. Dr. Boustani is the Founding Chief Innovation and Implementation Officer for the Indiana University Center for Health Innovation and Implementation Science. Over the past decade, Dr. Boustani has built a clinical laboratory within two health care systems in Indiana; Indiana University Health, a state wide system that includes 18 hospitals; and Eskenazi Health, a safety net health system serving the needs of underprivileged Marion County residents in Indianapolis. He has used this clinical laboratory to train clinical investigators who have successfully received career development awards from the NIH and has developed a graduate certificate in Innovation and Implementation Science to provide the country with transformational agents who are skilled in building learning health care systems (www.hii.iu.edu). In the fall of 2015, Dr. Boustani became the PI of the CMS funded Great Lakes Practice Transformation Network (1L1CMS331444-01-00). On this project, Dr. Boustani will service as the site PI for Regenstrief, ensuring the success of the research assistants and research manager described in the subaward budget.

(Advisor,

Subaward to Regenstrief ([redacted]):

To conduct the human subjects research, headed by Dr. Boustani. See attached subaward budget and justification. This is for budget period 1 of the subaward.

Server ([redacted]:

[redacted] bill for a capable dedicated server for [redacted]/month, as evidenced previously. This relatively powerful, secure, and reliable server will in Phase II be dedicated to hosting the entire technology platform for patients at Regenstrief.

LTE Internet Access ([redacted]): For an average of [redacted] SIM card for LTE Internet access. [redacted]

[redacted]

ASR Cloud Service [redacted]: Google Cloud Speech or equivalent better solution for automatic 3rd party transcription of up to [redacted].

Indirect Costs:

care.coach does not yet have a negotiated indirect cost rate. The company's indirect cost rate will be [redacted] Part of the indirect cost will go to rent and utility payment (please refer to the Letter of Support attachment for rent details). Additionally, care.coach is required to carry a significant amount of liability and professional insurance in order to maintain its contracts with certain healthcare providers.

Fee:

care.coach requests a 7% fee. These funds will be used to [redacted]

Phase II Year 2 Budget Justification

Senior/Key Persons:

Victor Wang (PI, [redacted]). Mr. Wang is CEO of care.coach. He has a broad background in robotics and human-machine interaction, with specific training and expertise in teleoperation, medical devices, human factors, and clinical research, including work with hospitals and IRB-approved study protocols. As an awardee or key consultant on several university- and externally-funded grants, Mr. Wang developed much of the groundwork for the proposed research by conceptualizing and implementing the techno-organizational platform required to scale a human-software hybrid avatar solution, and by establishing strong ties with healthcare providers and academia. Mr. Wang will administer the project's staffing, intellectual property protection, and budget, as well as all aspects of technology design, development and execution. As the care.coach Privacy and Information Security Officer, Mr. Wang will also ensure that all relevant institutional policies are upheld.

Brittany Wang (Co-Investigator, [redacted]). Mrs. Wang is Senior Program Manager of care.coach and has a Master's degree in Gerontology, with extensive work experience leading activities, life enrichment/engagement, and memory care programs for senior care and dementia care providers. In Phase II Year 2, she will continue to maintain the day-to-day efficacy of our system during the human subjects research by managing the health advocate team and coordinating with our care.coach technical staff and clinical/research partners on meeting product/operational/data requirements. She will also advise on the ASR/NLP-human handoff interface and will train the health advocates in the use of the new interface, managing the success of this major change in health advocate workflow.

Other Personnel:

Software Engineer, Machine Learning [redacted]). This engineer in Phase II Year 2 will continue to improve all the machine learning systems, and will be responsible for preparing all machine learning and ASR/NLP [redacted]

Software Engineer, Android ([redacted]). This engineer will be responsible for the ongoing implementation and improvement of our Android side software, with focus on [redacted]

Software Engineer, Web ([redacted]). This engineer will focus on the ongoing improvement of the dispatch system and the health advocate interface, and will measure and iterate on the success of our SBIR work to fully automate at least 1/3 of all of our avatar [redacted]

Travel ([redacted]):

Domestic Travel: [redacted]

Conferences: [redacted]

Other Direct Costs:

Publication Costs ([redacted]):

For publication of our achievements in research/industry journals.

Consultant Services ([redacted]: *(Note that based on the scientific reviewer feedback, we are adding Dr[redacted] here, and that based on NINR guidance on another award, we are moving Dr. Shuo Deng from Key Persons to the consultant category because she is paid as such rather than as an employee on payroll. [redacted] budgets come out of the previous budget for [redacted] resulting in no net change in budget.)*

[redacted] = [redacted] [redacted] is an expert in machine learning and speech recognition, with special experience in healthcare. He will leverage his expertise to advise and manage the success of the machine learning engineering and ASR effort.

[redacted] [redacted]/hr = [redacted]). [redacted] is an expert in full-stack software development, natural language processing, natural language generation, dialog management, machine learning, conversational interfaces, embodied interaction, and social robotics. He will work with [redacted] to manage the success of the NLP engineering effort and of the integration with the dispatch system, as well as the design of dialog and natural language generation algorithms to maintain novelty and engagement over time.

Transcription ([redacted] at [redacted]/hr, to ensure that all new training data collected from Regenstrief patient-avatar conversations are incorporated into the learning model, even if all available ASR engines have poor recognition.

Prof. Malaz Boustani (Co-Investigator & Regenstrief Site PI, [redacted]. Dr. Boustani is a senior implementation scientist with extensive experience in mentoring junior investigators and conducting implementation research with a main focus on developing tools, processes, and strategies to rapidly implement evidence-based and cost-effective health care solutions in the real world. Dr. Boustani is the Founding Chief Innovation and Implementation Officer for the Indiana University Center for Health Innovation and Implementation Science. Over the past decade, Dr. Boustani has built a clinical laboratory within two health care systems in Indiana; Indiana University Health, a state wide system that includes 18 hospitals; and Eskenazi Health, a safety net health system serving the needs of underprivileged Marion County residents in Indianapolis. He has used this clinical laboratory to train clinical investigators who have successfully received career development awards from the NIH and has developed a graduate certificate in Innovation and Implementation Science to provide the country with transformational agents who are skilled in building learning health care systems (www.hii.iu.edu). In the fall of 2015, Dr. Boustani became the PI of the CMS funded Great Lakes Practice Transformation Network (1L1CMS331444-01-00). On this project, Dr. Boustani will service as the site PI for Regenstrief, ensuring the success of the research assistants and research manager described in the subaward budget.

[redacted] (Advisor, [redacted]; and [redacted] (Advisor, [redacted] ment.

Subaward to Regenstrief [redacted]):

To conduct the human subjects research, headed by Dr. Boustani. See attached subaward budget and justification. This is for budget period 2 of the subaward.

Server ([redacted]):

Rackspace bill for a capable dedicated server for 12 months at [redacted]/month, as evidenced previously. This relatively powerful, secure, and reliable server will in Phase II be dedicated to hosting the entire technology platform for patients at Regenstrief.

LTE Internet Access ([redacted]): For an average of [redacted] SIM card for LTE Internet access. [redacted]

ASR Cloud Service ([redacted]): Google Cloud Speech or equivalent better solution for automatic 3rd party transcription of substantially all the protocol-driven patient response audio that we expect to gather in Phase II Year 2.

Indirect Costs:

care.coach does not yet have a negotiated indirect cost rate. The company's indirect cost rate will be [redacted] Part of the indirect cost will go to rent and utility payment (please refer to the Letter of Support attachment for rent details). Additionally, care.coach is required to carry a significant amount of liability and professional insurance in order to maintain its contracts with certain healthcare providers.

Fee:

care.coach requests a 7% fee. These funds will be used to [redacted]

EVALUATION OF FINANCIAL MANAGEMENT SYSTEMS
(Abbreviated Questionnaire)*

A. ACCOUNTING SYSTEM:

	YES	NO	COMMENT
1. Is there a chart of accounts?	✔		See attached financial statements (accounts with no balance may not be shown).
2. Does the accounting system include a project cost ledger providing for the recording of expenditures for each program by required budget cost categories?	✔		Achieved through cost tracking codes within our accounting system.
3. How do employees account for their time and effort? Please explain.			We use Clockify.me, a software time tracking solution that helps us to implement our Financial Controls Policy.

B. FINANCIAL CAPABILITY:

	YES	NO	COMMENT
1. Does the organization prepare financial statements at least annually? (Provide a copy of latest Balance Sheet and Income Statement.)	✔		Attached.
2. Has the organization established line(s) of credit? If so, identify source and amount.	✔		[redacted]

C. BUDGETARY CONTROLS:

	YES	NO	COMMENT
1. Are there budgetary controls in effect (e.g. comparison of budget with actual expenditures on a monthly basis) to preclude drawing down federal funds in excess of:	✔		Per our Financial Controls Policy, quarterly financial statements broken down by project (direct cost tracking code) will be generated by Treasurer with comparison to budgeted amounts for each account, with review by Secretary. Hourly wage workers have a weekly maximum number of hours workable, to stay within budget from week to week. Primarily this applies to our health advocates.

	YES	NO	COMMENT
a. Total funds authorized on the Notice of Grant Award;	✔		This would correspond to the authorized direct costs on the Notice of Award compared to the total expenditures under the project tracking code.
b. Total funds available for any cost category if restricted on the Notice of Grant Award	✔		This would correspond to the budget for the restricted cost category on the Notice of Award compared to the expenditures under a particular account under the “Direct Program Costs” category (e.g. “Direct Cellular Data”) when reported by tracking code.

D. INTERNAL CONTROLS

	YES	NO	COMMENT
1. What safeguards has the grantee instituted to ensure adequate internal controls in the company? Please describe. Some examples might be:			See below:
a. Accounting entries are supported by appropriate documentation; e.g. purchase orders and vouchers.	✔		Excerpted from various sections of our Financial Controls Policy: • Any reimbursements to employees will be performed through the payroll software and must be evidenced by receipts documenting the nature and purpose of the spending, and written authorization of spending. • Check payments should have a notation regarding the purpose of the payment written on the check. An electronic scan/image of the check should be saved with the invoice or purchase order documenting the purpose of the check. • There is to be no petty cash fund. Any cash withdrawn must be immediately spent for a specific purpose, with documentation, with any remainder immediately re-deposited. • A backup of the updated accounting software database must be sent to Secretary for review and archival on a separate computer running its own instance of the accounting software, along with documentation of receipts/invoices for payments (receipts may also take the form of electronic payment records from PayPal or credit card statements that identify what was purchased).

	YES	NO	COMMENT
b. Separation of responsibility in the receipt, payment, and recording of cash.	✔		Per our Financial Controls Policy, Secretary receives and deposits cash, Treasurer records cash, President (who is currently the same person as Treasurer) has ultimate payment authority, but employees may also have corporate credit cards, and Secretary reviews all payment and other accounting records as an internal auditor.

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2017 Year-End Balance Sheet

As at 12/31/2017

	12/31/2017
Assets	
1000 Cash (Credit Cards as Contra-Asset)	[redacted]
Liabilities	
[redacted]	[redacted]
Net assets	[redacted]
Equity	
Starting balance equity	[redacted]
3001 Retained earnings	[redacted]
[redacted]	[redacted]
Total — Equity	[redacted]
Total equity	[redacted]

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2017 Annual Income Statement

For the period from 1/1/2017 to 12/31/2017

	12/31/2017
Income	
4000 Sales	[redacted]
4010 Grant Revenue	[redacted]
4020 [redacted]	[redacted]
Total — Income	[redacted]
Less: Fringe Benefits (COGS/OpEx Proportional to Other Groups)	[redacted]
6025 Payroll Taxes	[redacted]
Less: Overhead (COGS)	[redacted]
7010 Overhead Health Advocate Wages & Bonuses	[redacted]
7020 Overhead Training & Background Checks	[redacted]
7200 [redacted]	[redacted]
7500 Overhead Server Hosting	[redacted]
7510 Overhead Cellular Data	[redacted]
7515 Overhead Software Licenses	[redacted]
7700 Overhead Postage	[redacted]
Total — Overhead (COGS	[redacted]
Less: G&A (OpEx)	[redacted]
8005 G&A Salaries & Wages (R&D)	[redacted]
8010 G&A Salaries & Wages (Non-Sales/Marketing, Non-R&D)	[redacted]
8020 Office Rent	[redacted]
8030 Office Internet	[redacted]
8040 Telephone	[redacted]
8060 Office Equipment (Expendable)	[redacted]
8080 Office Supplies	[redacted]
8090 G&A Travel	[redacted]
8100 G&A Independent Consultants (R&D)	[redacted]
8105 G&A Independent Consultants (Non-Sales/Marketing, Non-R&D)	[redacted]
8110 Legal fees	[redacted]
8115 Accounting fees	[redacted]
8118 Bank charges	[redacted]
8120 Insurance	[redacted]
8130 Permits & Fees	[redacted]
8140 Professional Dues & Subscriptions	[redacted]
8145 G&A Software Licenses	[redacted]
8148 G&A Server Hosting	[redacted]
8150 G&A Postage	[redacted]
8170 Taxes (Non-Federal)	[redacted]
8175 Taxes (Federal)	[redacted]
8180 [redacted]	[redacted]
8190 [redacted]	[redacted]

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2017 Annual Income Statement

For the period from 1/1/2017 to 12/31/2017

	12/31/2017
8200 [redacted]	[redacted]
Total — G&A (OpEx)	[redacted]
Less: Grant Unallowable (OpEx)	
9000 Interest Expense	[redacted]
9015 Advertising and promotion 9040	[redacted]
Total [redacted]	[redacted]
	[redacted]
Net profit (loss)	[redacted]

SBIR Funding Agreement Certification

Grant Contract Number:

Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)): Victor Wang

All small businesses that are selected for award of an SBIR funding agreement must complete this certification at the time of award and any other time set forth in the Notice of Award or Contract Award that is prior to performance of work under this award. This includes checking all of the boxes and having an authorized officer of the awardee sign and date the certification each time it is requested.

Please read carefully the following certification statements. The Federal government relies on this information to determine whether the business is eligible for a Small Business Innovation Research (SBIR) Program award. A similar certification will be used to ensure continued compliance with specific program requirements during the life of the funding agreement. The definitions for the terms used in this certification are set forth in the Small Business Act, SBA regulations (13 C.F.R. Part 121), the SBIR Policy Directive and also any statutory and regulatory provisions references in those authorities.

If the Grants Management or Contracting Officer believes that the business may not meet certain eligibility requirements at the time of award, they are required to file a size protest with the U.S. Small Business Administration (SBA), who will determine eligibility. At that time, SBA will request further clarification and supporting documentation in order to assist in the verification of any of the information provided as part of a protest. If the Grants Management or Contracting Officer believes, after award, that the business is not meeting certain Notice of Award requirements, the agency may request further clarification and supporting documentation in order to assist in the verification of any of the information provided.

Even if correct information has been included in other materials submitted to the Federal government, any action taken with respect to this certification does not affect the Government's right to pursue criminal, civil, or administrative remedies for incorrect or incomplete information given in the certification. Each person signing this certification may be prosecuted if they have provided false information.

The undersigned has reviewed, verified and certifies that (all boxes must be checked):

1. The business concern meets the ownership and control requirements set forth in 13 C.F.R. § 121.702.

   ☒ Yes ☐ No

2. If a corporation, all corporate documents (articles of incorporation and any amendments, articles of conversion, by-laws and amendments, shareholder meeting minutes showing director elections, shareholder meeting minutes showing officer elections, organizational meeting minutes, all issued stock certificates, stock ledger, buy-sell agreements, stock transfer agreements, voting agreements, and documents relating to stock options, including the right to convert non-voting stock or debentures into voting stock) evidence that it meets the ownership and control requirements set forth in 13 C.F.R. § 121.702.

   ☐ Yes ☐ No ☐ N/A Explain why N/A:

3. If a partnership, the partnership agreement evidences that it meets the ownership and control requirements set forth in 13 C.F.R. § 121.702.

   ☐ Yes ☐ No ☒ N/A Explain why N/A:

4. If a limited liability company, the articles of organization and any amendments, and operating agreements and amendments, evidence that it meets the ownership and control requirements set forth in 13 C.F.R. § 121.702.

   ☐ Yes ☐ No ☒ N/A Explain why N/A:

5. The birth certificates, naturalization papers, or passports show that any individuals it relies upon to meet the eligibility requirements are U.S. citizens or permanent resident aliens in the United States.

   ☐ Yes ☐ No ☐ N/A Explain why N/A:

6. It has no more than 500 employees, including the employees of its affiliates.

   Yes☐ ☐ No

7. SBA has not issued a size determination currently in effect finding that this business concern exceeds the 500 employee size standard.

   ☐ Yes ☐ No

8. During the performance of the award, the principal investigator will spend more than half of his/her time as an employee of the awardee or has requested and received a written deviation from this requirement from the Grants Management or Contracting Officer.

   ☐ Yes ☐ No Deviation approved in writing by Grants Management or Contracting Officer: %

9. All, essentially equivalent work, or a portion of the work proposed under this project (check the applicable line):

   Has not been submitted for funding by another Federal agency

   ☐ Has been submitted for funding by another Federal agency but has not been funded under any other Federal grant, contract, subcontract, or other transaction.

   ☐ A portion has been funded by another grant, contract, or subcontract as described in detail in the proposal and approved in writing by the Grants Management or Contracting Officer.

10. During the performance of award, it will perform the applicable percentage of work unless a deviation from this requirement is approved in writing by the Grants Management or Contracting Officer (check the applicable line and fill in if needed):

    ☐ SBIR Phase I: at least two-thirds (66 2/3%) of the research

    ☐ SBIR Phase II: at least half (50%) of the research

    ☐ Deviation approved in writing by the Grants Management or Contracting Officer: %

11. During performance of award, the research/research and development will be performed in the United States unless a deviation is approved in writing by the Grants Management or Contracting Officer.

    ☐ Yes ☐ No

12. During the performance of award, the research/research and development will be performed at my facilities with my employees, except as otherwise indicated in the SBIR application and approved in the Notice of Award or Contract Award.

    ☐ Yes ☐ No

13. It has registered itself on SBA's database as majority-owned by venture capital operating companies, hedge funds or private equity firms.

    ☐ Yes ☐ No ☐ N/A Explain why N/A:

14. It is a Covered Small Business Concern (a small business concern that: (a) was not majority-owned by multiple venture capital operating companies (VCOCs), hedge funds, or private equity firms on the data on which it submitted an application in response to an SBIR solicitation; and (b) on the date of the SBIR award, which is made more than 9 months after the closing date of the solicitation, is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms).

    ☐ Yes ☐ No

NIH & CDC Small Business Innovation Research Program
Certification for Applicants That Are Majority-Owned by Multiple Venture Capital Operating Companies, Hedge Fund, or Private Equity Firms

Any small businesses that are majority-owned by multiple venture operating companies (VCOCs), hedge funds or private equity firms and are submitting an application for an SBIR funding agreement must complete this certification prior to submitting an application. This includes checking all of the boxes and having an authorized officer of the applicant organization sign and date the certification each time it is requested.

Please read carefully the following certification statements. The Federal government relies on the information to determine whether the business is eligible for a Small Business Innovation Research (SBIR) Program award and meets the specific program requirements during the life of the funding agreement. The definitions for the terms used in this certification are set forth in the Small Business Act, SBA regulations (13 C.F.R. Part 121), the SBIR Policy Directive and also any statutory and regulatory provisions referenced in those authorities.

If the funding agreement officer believes that the business may not meet certain eligibility requirements at the time of award, they are required to file a size protest with the U.S. Small Business Administration (SBA), who will determine eligibility. At that time, SBA will request further clarification and supporting documentation in order to assist in the verification of any of the information provided as part of a protest. If the funding agreement officer believes, after award, that the business is not meeting certain funding agreement requirements, the agency may request further clarification and supporting documentation in order to assist in the verification of any of the information provided.

Even if correct information has been included in other materials submitted to the Federal government, any action taken with respect to this certification does not affect the Government's right to pursue criminal, civil or administrative remedies for incorrect or incomplete information given in the certification. Each person signing this certification may be prosecuted if they have provided false information.

The undersigned has reviewed, verified and certifies that (all boxes must be checked):

1. The applicant is NOT more than 50% owned by a single VCOC, hedge fund or private equity firm.

   ☐ Yes ☐ No

2. The applicant is more than 50% owned by multiple domestic business concerns that are VCOCs, hedge funds, or private equity firms.

   ☐ Yes ☐ No

3. I have registered with SBA at www.SBIR.gov as a business that is majority-owned by multiple VCOCs, hedge funds or private equity firms.

   ☐ Yes ☐ No

☒ I understand that the information submitted may be given to Federal, State and local agencies for determining violations of law and other purposes.

☒ All the statements and information provided in this form and any documents submitted are true, accurate and complete. If assistance was obtained in completing this form and the supporting documentation, I have personally reviewed the information and it is true and accurate. I understand that, in general, these statements are made for the purpose of determining eligibility for an SBIR funding agreement and continuing eligibility.

☒ I understand that the certifications in this document are continuing in nature. Each SBIR funding agreement for which the small business submits an offer or application or receives an award constitutes a restatement and reaffirmation of these certifications.

☒ I understand that I may not misrepresent status as small business to: 1) obtain a contract under the Small Business Act; or 2) obtain any benefit under a provision of Federal law that references the SBIR Program.

☐ I am an officer of the business concern authorized to represent it and sign this certification on its behalf. By signing this certification, I am representing on my own behalf, and on behalf of the SBIR applicant or awardee, that the information provided in this certification, the application, and all other information submitted in connection with this application, is true and correct as of the date of submission. I acknowledge that any intentional or negligent misrepresentation of the information contained in this certification may result in criminal, civil or administrative sanctions, including but not limited to:

(1) fines, restitution and/or imprisonment under 18 U.S.C. §1001;

(2) treble damages and civil penalties under the False Claims Act (31 U.S.C. §3729 et seq.);

(3) double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. §3801 et seq.);

(4) civil recovery of award funds,

(5) suspension and/or debarment from all Federal procurement and nonprocurement transactions (FAR Subpart 9.4 or 2 C.F.R. part 180); and

(6) other administrative penalties including termination of SBIR/STTR awards.

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Assurance Information

Assurance: Care.coach

Located at : [redacted]
Expires : 8/30/2022

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Note: No Assurance Components Identified.

IRBs linked to this Assurance

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