Appendix 4.1: Statement of Work

Proposal Number: MTEC-20-12-COVID19-050
Organization: Philips North America, LLC
Title: Philips North America, LLC's response to Wearable Diagnostic for Detection of COVID-19 Infection ACURO and/or HRPO approval needed: HRPO Approvals Needed

Introduction/Background

Philips is a health technology company focused on improving lives across the healthcare continuum – from healthy living and prevention, to diagnosis, treatment, and home care. Philips has helped build and shape markets with meaningful innovation for the last 125 years. We partner with our clients to transform how healthcare is delivered and experienced. We are a leader in diagnostic imaging, image-guided therapy, patient monitoring, and health informatics, as well as in consumer health and home care.

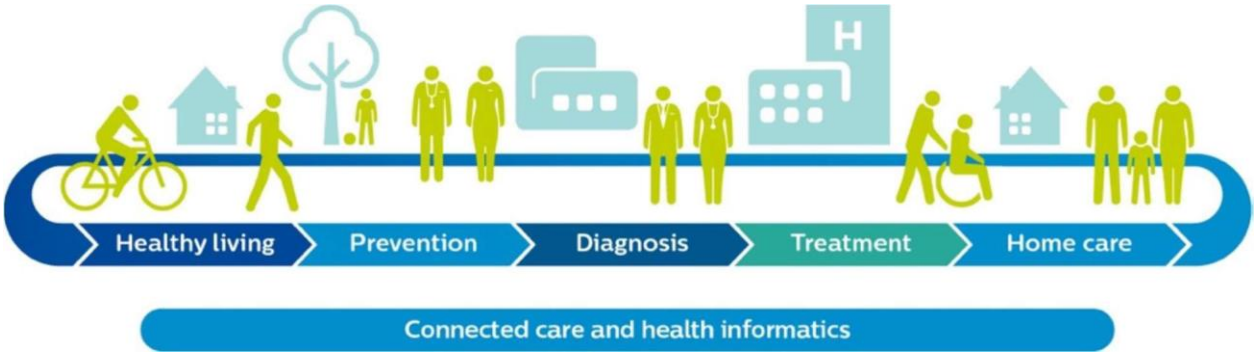

Figure 1: Health cycle

With a global and long-term presence in the personal and professional healthcare worlds, Philips aspires to grow our leadership in health technology and, most importantly, achieve our vision of improving the lives of 3 billion people per year by 2030.

We take a holistic view of the health journey – starting with healthy living and prevention, precision diagnosis and personalized treatment, through to care in the home, where the cycle to healthy living should begin again. Leveraging expertise in both clinical and consumer technologies, we help healthcare providers, payers, consumers, and companies address the challenges they face by developing and delivering solutions that address the real needs of all players in the care ecosystem.

(b) (4) ., is a continuous health monitoring and clinical intelligence company enabling remote patient monitoring (RPM) at scale. Its medical-grade Data-as-a-Service (DaaS) platform seamlessly captures minute-to-minute vital signs, physiological biometrics, and symptomatic events through an effortless patient experience. The FDA-cleared (b) (4) device makes remote monitoring of symptoms associated with COVID-19 and early detection simple. Through the platform's advanced analytics, clinicians have access to high-resolution patient trending and reporting to enable medical-grade care in the home.

Scope/Project Objective

Scope Statement

The (b) (4), including remote patient monitoring solutions, together with the (b) (4), includes our clinical care management platform and both high-touch and low-touch options, depending on patient needs and preference, and clinical care protocols. As facilities can cover a wide range of care services, we offer analytics capabilities and a scalable care management approach, which incorporates our remote patient monitoring, medication adherence, and population health management solutions. Manage populations in post-acute settings

For patients with chronic diseases, returning home from the hospital can pose a unique set of challenges. For this high-risk immediate post-discharge period, our telehealth-enabled program can help clinicians track these patients daily while their status stabilizes, minimizing their chances of health decline or being readmitted to the hospital. The program lets clinicians monitor patients' health remotely to identify symptoms and enable early intervention.

Figure 2. Philips Process

Our team wants to fully enable the ability to manage different health populations by delivering programs to engage and motivate patients toward a healthier lifestyle by delivering a blueprint for success.

Holistic Operating Model	Embedded Clinical Expertise	Positive Outcomes
• Tailored program design, resource planning, care team collaboration, and implementation • Inventory and/or monitoring of incoming patient data can be managed by Philips or you, the customer	• Library of customizable care protocols based on patient condition, co-morbidities, and length-of-stay duration • Patient selection criteria • Patient stratification tools • Reporting for program administrators and physician	• Telehealth programs are designed to help streamline clinical workflow; and can help lead to lower mortality, shorter length of stay, fewer hospital readmissions, and potentially lower long-term healthcare costs

Figure 3: Programmatic approach

Philips eCareCoordinator - Clinical Platform

Clinical Workflow and Efficiency

The eCareCoordinator telehealth software platform lets clinicians access their institution's library of pre-assembled care protocols based on best practices, guidelines, and organizational requirements.

Once a patient is enrolled, the clinician assigns the patient a care protocol and personalizes it. The clinician can then remotely monitor the patient's vital signs, send short surveys about the patient's health status, and conduct ad hoc and scheduled video calls. Patient responses and measurements are automatically transmitted to the care team.

Based on this combination of objective data and subjective responses, the Philips eCareCoordinator platform helps prioritize populations enabling clinicians to identify and provide care to the patients most at-risk through an interactive dashboard.

They can also communicate and coordinate care within the system through tasks, manage care plans, run and send reports, and assess patient care at a population and individual level.

Philips eCareCoordinator platform

- Web-based application with video view into patients' environments and behaviors to collaboratively manage readmission risk factors
- Pre-defined, automated daily patient interaction protocols that customer can fully author and/or customize
- Population triage dashboard with advanced clinical algorithms to help prioritize at-risk patients for intervention
- Workflow efficiency and care team collaboration promoted by embedded tools
- Care documentation via structured clinical notes with autofill, spell check and reporting capability
- Clinical and operational performance reporting

Figure 4: Sample Data Reports

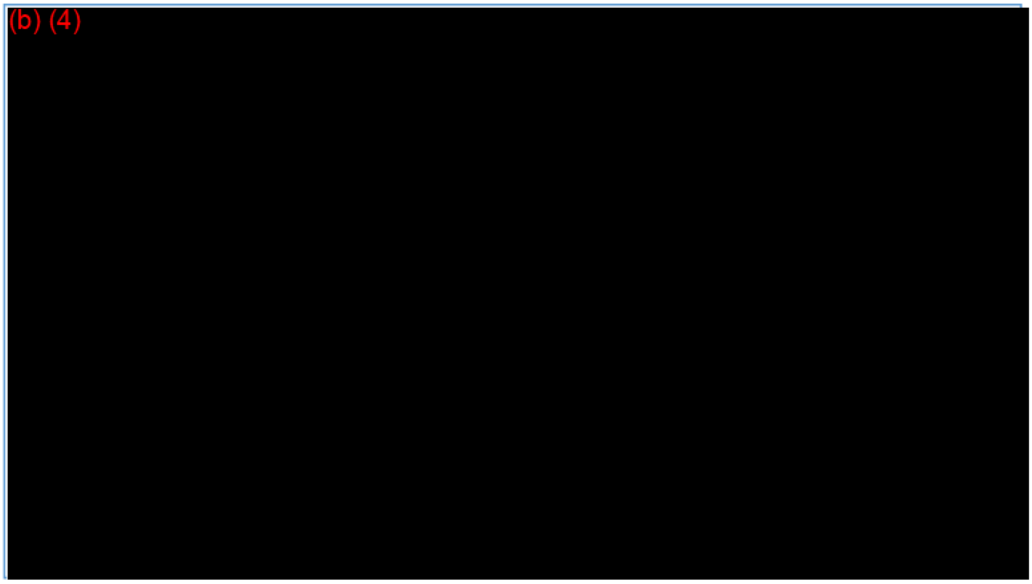

Figure 5: (b) (4) Data Fusion Examples

(b) (4)

(b) (4)

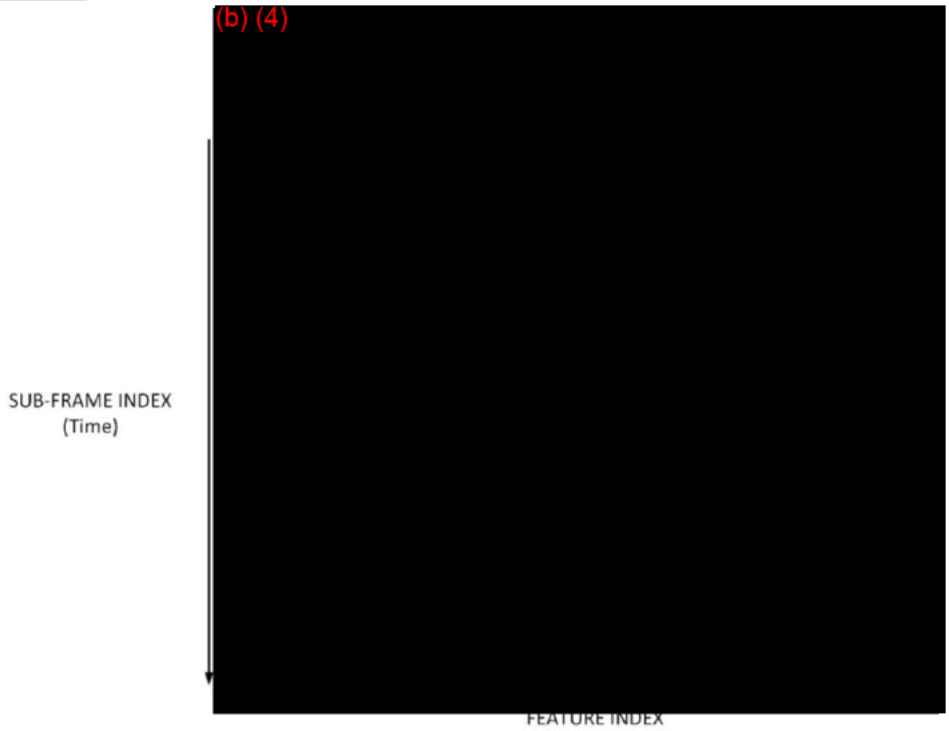

Figure 6: Feature Extraction Matrix for Machine Learnings

Under this methodology, multiple approaches can be used to infer and classify the signals. The figure below shows a visual representation of two cough types that would go into a convolutional neural network to perform image recognition on the "feature images."

Figure 7: Cough Type 1 vs. Cough Type 2

Early symptoms such as muscle fatigue are expected to show up in a meaningful perturbation as early symptoms of muscle fatigue present by combining the relative activity levels and body position of the patient. The figure below illustrates the various levels of energy patterns that exist through different behaviors which we analyze and classify.

Figure 8: Minute AC Data

Another example of data fusion results from the analysis of a patient's body position and torso incline angle while laying down. A resulting correlation can be identified between respiratory rate and incline angle that could be used as an early predictor of breathing difficulties.

Figure 9: Data fusion

Objectives/Goals:

Overall Project PM

- Goal: Complete the overall project on-time and on-budget with successful outcomes

Deliverables

  - Monthly status updates: visual dashboard for all workstreams/deliverables
  - Issue/Risks Tracker: Identification and mitigation of issues and risks

- Governance: Daily status meetings with the project team to discuss overall project plan and progress on an integrated project schedule with visuals

Task 1

- Goal: (b) (4) (b) (4)
- Collecting data: (b) (4) (b) (4)
- Evaluation and Reporting of Outcomes: Compile and track measurements and feedback from users throughout the system
- Detection Algorithm: Validate the inference engine and model basic logic
- Regulatory Guidelines and Patients Surveys: Used to validate diagnosis based on measurements data

Task 2

- Goal: (b) (4)
- Usability: Plan to test the solution with selected partners and incorporate feedback from users. It also includes assessment of scalability, reliability, interface, and user environment testing.
- Training: Provide training to the patients on the location of (b) (4)
- Criteria: (b) (4) (b) (4)

Task 3

- Goal – (b) (4) (b) (4)
- Collection and Storage: Stored in the cloud.
- Solution Improvement Plan: (b) (4) (b) (4)

Deliverables

The following table represents the Philips' team deliverables by task.

Deliverable	Description
Deliverable 1	(b) (4)
Deliverable 2	(b) (4)
Deliverable 3	(b) (4)
Deliverable 4	(b) (4)
Deliverable 5	(b) (4)
Deliverable 6	(b) (4)
Deliverable 7	(b) (4)
Deliverable 8	(b) (4)
Deliverable 9	(b) (4)
Deliverable 10	(b) (4)

Table 1: Milestone Payment Schedule

MTEC Milestone #	Significant Event / Accomplishment	Due Date	Government Funds
1	Project Kickoff	7/22/2020	(b) (4)
2	Setup and implementation	8/1/2020	(b) (4)
3	Bimonthly Report 1 (July – August, Technical and Business Reports)	8/25/2020	(b) (4)
4	Submit for HRPO Approvals	8/30/2020	(b) (4)
5	Regulatory Guidelines and Patient Surveys	8/30/2020	(b) (4)
6	Setup and configuration of enrollment tools	8/30/2020	(b) (4)
7	Algorithm Adjustment 1	8/30/2020	(b) (4)
8	Development and implementation of protocols	9/1/2020	(b) (4)
9	1st subject screened, randomized and enrolled in the study	9/1/2020	(b) (4)
10	Monthly Evaluation and Reporting of Outcomes	9/30/2020	(b) (4)
11	Research staff trained	10/15/2020	(b) (4)
12	Bimonthly Reports 2 (September - October, Technical and Business Reports)	10/25/2020	(b) (4)
13	Data Management system completed	10/30/2020	(b) (4)
14	Algorithm Adjustment 2	10/30/2020	(b) (4)
15	Solution improvement plan	10/30/2020	$0.00
16	Complete 50% patient enrollment	11/15/2020	(b) (4)
17	Electronic Report Forms Developed	12/1/2020	(b) (4)
18	Bimonthly Report 3 (November - December, Technical and Business Reports)	12/25/2020	(b) (4)
19	Algorithm Adjustment 3	12/30/2020	(b) (4)
20	Complete 75% patient enrollment	1/15/2021	(b) (4)
21	Complete 100% patient enrollment	2/15/2021	(b) (4)
22	Bimonthly Report 4 (January - February, Technical and Business Reports)	2/25/2021	(b) (4)
23	Algorithm Adjustment 4	2/28/2021	(b) (4)
24	Report results from data analysis	3/15/2021	(b) (4)
25	Solution improvement plan	4/30/2021	(b) (4)
26	Monthly status updates and visual dashboard	4/30/2021	(b) (4)
27	Issues/Risk Tracker	4/30/2021	(b) (4)
28	Data collection and storage	4/30/2021	(b) (4)
29	Usability testing	4/30/2021	(b) (4)
30	Final Reports (Technical and Business Reports)	4/30/2021	(b) (4)
	Total		$2,753,675.00

Bi-monthly Reports

Philips will provide the required reports in the requested format.

Final Technical Report

Philips will provide the required reports in the requested format.

Final Business Status Report

Philips will provide the required reports in the requested format.