Statement of Work

Proposal Number: MTEC-20-12-COVID19-Diagnostics-095
Organization: Empatica, Inc.
Title: FALCON - First ALert for COVID-19 ONset
ACURO and/or HRPO approval needed: HRPO Approvals Needed.

Introduction/Background

SARS-CoV-2 has brought the world to standstill in a matter of months. While the global scientific community has ramped up its efforts to find a solution, no effective treatment or vaccine has been found to date. And while testing capabilities for both infection (RT-PCR) and prior-contagion (antibody testing) are growing, most individuals are unwilling or unable to partake in daily testing. Additionally, daily testing gives no indication of potential disease severity or follow up understanding of symptom severity. With the economy dipping to meet this standstill, it is imperative to allow critical workers, students and teachers, civilians, military personnel to safely reenter the workplace as well as a semblance of their daily lives. Since little is known as to how the virus will continue to spread, an early detection platform of COVID-19 contagion could prove essential in the coming years to help keep people safely back at work and active in their lives.

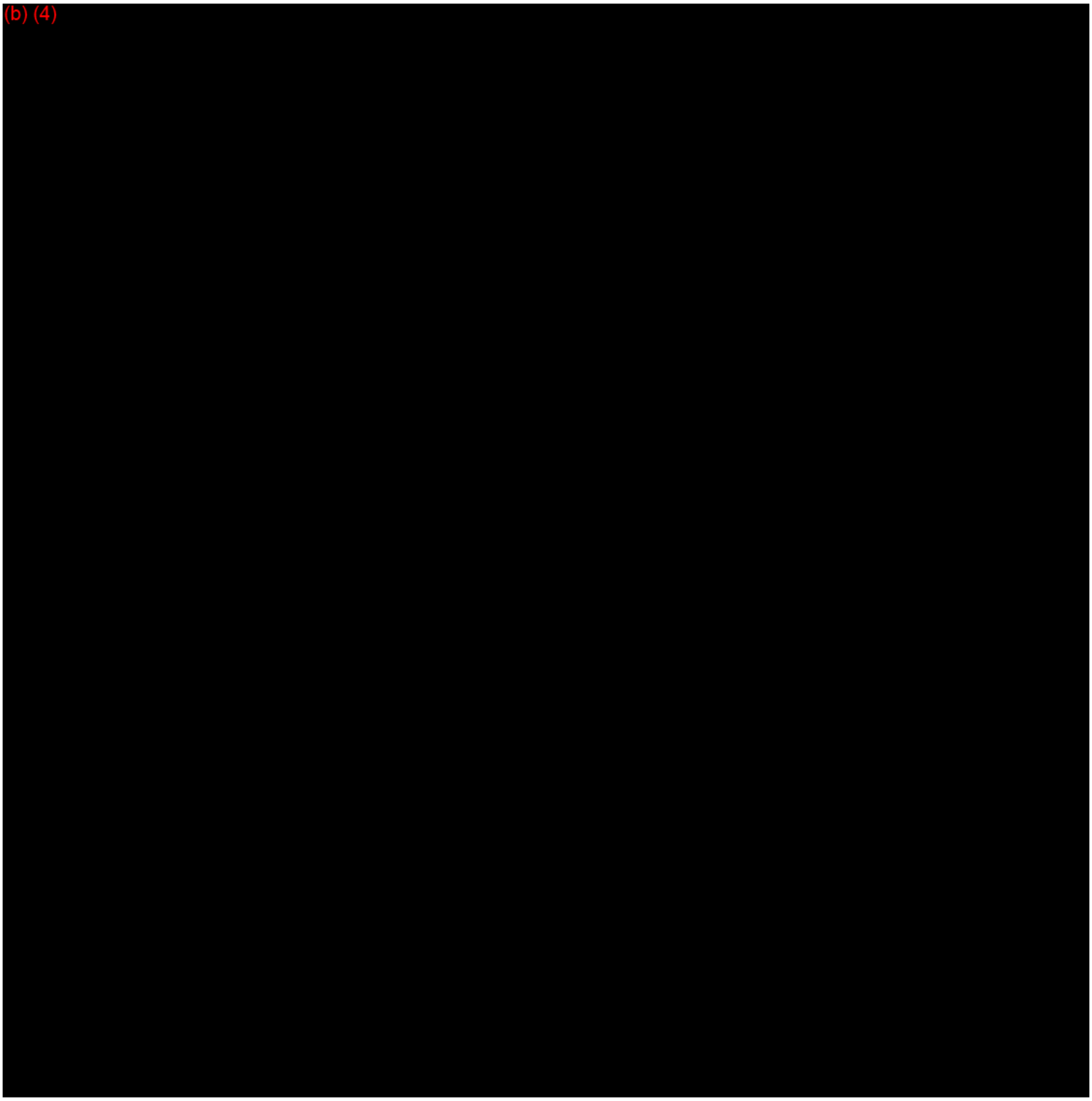
For the past year, Empatica (b) (4) . Our analysis from this initiative, plus an additional dataset from (b) (4) t, demonstrate our (b) (4)

(b) (4)

(b) (4) Empatica (b) (4) (b) (4) (b) (4) (b) (4) With IRB approval already in place, the materials prepared for an Emergency Use Authorization (EUA) to the FDA, and FDA compliant production expertise ready to start work for (b) (4) , the Empatica team is prepared to kick-off FALCON immediately to meet the Army's needs.

Empatica's (b) (4)

(b) (4)



Scope/Project Objective

The goal of (b) (4) (b) (4) Over the course of this initiative algorithm validation, regulatory approvals and regulatory-compliant production setup will run in parallel, in order for Empatica to be able to ship the complete product (device, algorithm for early detection, app for alerting, cloud platform for remote monitoring).

Within the scope of this project Empatica plans to (b) (4) (b) (4) (b) (4) This validation effort will occur on at-risk patients. (b) (4) (b) (4) (b) (4) Our data team has built the data pipeline and only needs to input cleaned and processed data for this validation. This will help further our regulatory strategy to bring (b) (4) to market. We've already prepared the materials for an EUA of the E4 hardware, software, and algorithm, which gives an early alert to a possible infectious respiratory disease. While awaiting EUA, Empatica is also (b) (4) Once De Novo approval has been given, we'll be able to submit for a 510(K) clearance of our next generation (b) (4) with the E4 as our predicate device. (b) (4) (b) (4) With the EUA materials already prepared for our early detection against infectious respiratory disease platform, we are well on our way with our regulatory plan, and will continue with a Q-Sub submission in the next weeks. Meanwhile, we will complete the necessary setup to put in place FDA compliant testing, manufacturing, and processes. Within the scope of FALCON, these activities will specifically include the minimal activities required for a FDA compliant setup.

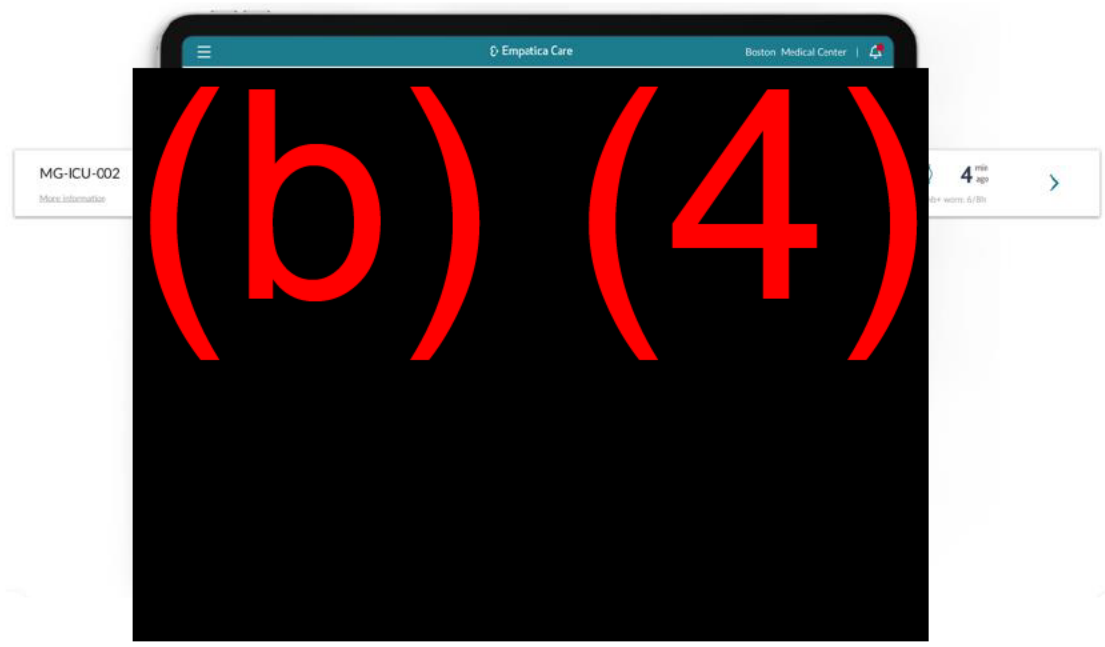
(b) (4) The tested hardware will consist of (b) (4), finalized and produced from our tested FDA compliant manufacturing line. (b) (4) (b) (4) or this purpose. The final tested platform (b) (4) (b) (4) will be tested on a target population of (b) (b) (4). Target cohorts will be selected from the general population: patients with pre-existing conditions, elderly individuals, and students and teachers among education environments. (b) (4) (b) (4) This will advance testing and validation within the target population, and de-risk the timing associated with the regulatory approval, therein strengthening its progress and the platform for consumer readiness.

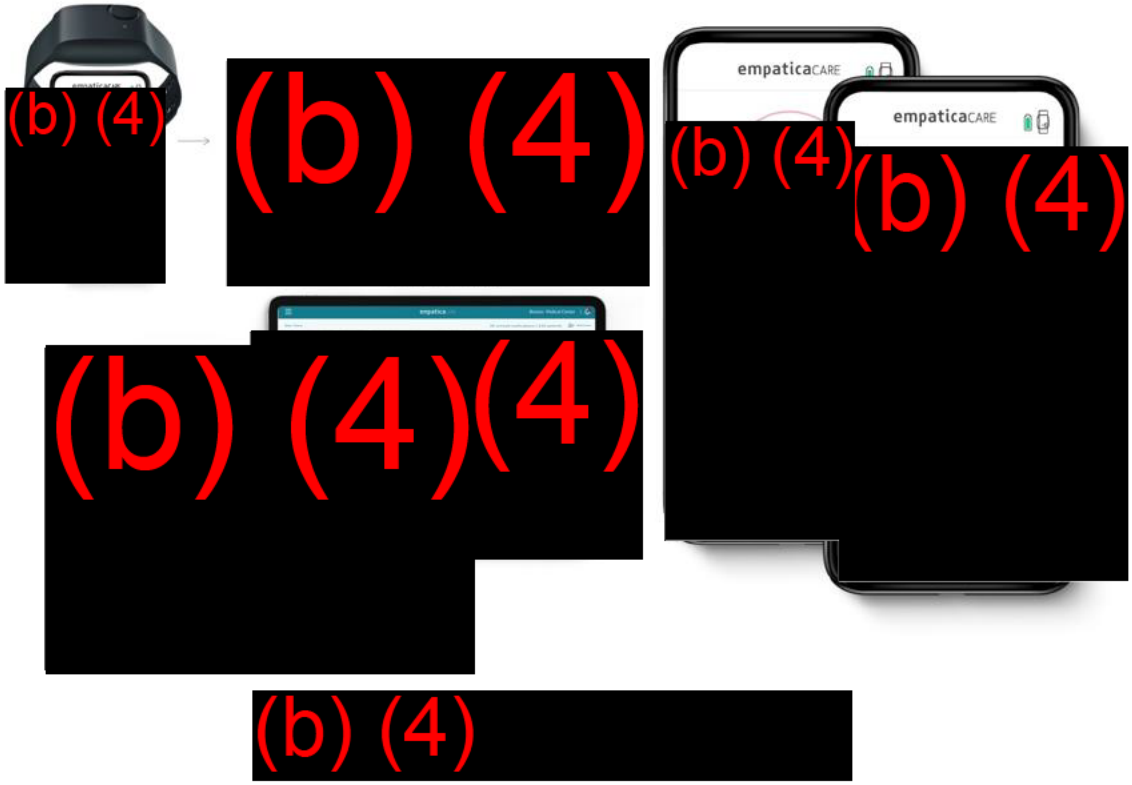
Major Milestones:

- Validation and performance metrics of early detection algorithm, Aura from completed clinical trial
- EUA and De Novo filing to FDA
- Successful testing of (b) (4)
- Successful testing (b) (4)
- Successful setup of required activities for FDA compliant manufacturing facility for (b) (4) and user acceptance of finalized product (b) (4) from an online clinical trial on the target population

Product Overview

E4 Device and Care mobile app


Empatica Care
Boston Medical Center
MG-ICU-002
(b) (4)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Requirements

The (b) (4) [redacted] Over the course of this initiative algorithm validation, regulatory approvals and FDA compliant manufacturing setup will run in parallel, in order for Empatica (b) (4) [redacted] The final IDE study activity incorporates deployment of the final product on the target population through a virtual and online clinical testing and validation of the platform's requirements.

Milestones

1. ***Clinical trial*** (b) (4) [redacted] - These milestones cover the work required for a successful validation of Empatica's existing algorithm for early detection of respiratory infection.
   1.1. **Clinical trial setup** - The team will prepare all the preliminary steps to launch the study, as it has successfully done in the past. It will procure devices (E4s and SpO2 sensors), set up the necessary cloud infrastructure, account management and swabs and reagents equipment. The outcome is the start of the study.
   1.2. **Last patient out** - Last patient out of the study will close the data collection phase.
   1.3. **Data processing** - The team will perform analysis of the data collected during the study, processing a performance analysis with the algorithm that has been previously developed by the company. The outcome of this milestone is the documentation required by FDA to be included in the upcoming DeNovo regulatory filing.

2. ***Regulatory filings*** - These milestones cover the regulatory work Empatica is performing to achieve the project ultimate goal. The costs associated to these activities are not included in the budget
   2.1. **EUA status (out of scope)** - The team already prepared the necessary documentation required to file an EUA to FDA, filing before project start.
   2.2. **De Novo filing (out of scope)** - The team will prepare the required documentation to complete an FDA filing.

3. ***Platform testing and service integration*** - These milestones cover the final validation and testing of the technology components included in the project. There are 3 main components:
   - **Product Package 1**: it includes the hardware device (b) (4) [redacted]) that have been previously developed by the company, including the embedded software. It also features the encrypted data transmission protocols from the device to the smartphone, and the relative SDK libraries embedded in Empatica's

proprietary mobile application, (b) (4). The activities performed within the scope of the SOW only refer to testing.

- **Product Package 2**: it includes all software layers of Empatica's clinical infrastructure, that have been developed and tested with thousands of institutional clients. (b) (4) (b) (4) (b) (4) The Aura algorithm, performing early detection of respiratory infection, runs on this system. The activities performed within the scope of the SOW only refer to testing.
- **Product Package 3**: it includes the front-end client application. Empatica (b) (4) (b) (4) (b) (4)

Relevant milestones pertaining to Platform testing and Service integration:

3.1. **Testing Product Package 3** - Front end testing according to the above mentioned Product Package 3 definition.

3.2. **Testing Product Package 2**

3.3. **Testing Product Package 1 v1** - This milestone refers to testing the specific integration of the

3.4. **Testing Product Package 1 v2** - This milestone refers to testing the specific integration of the

4. (b) (4) **manufacturing setup** - These milestones cover all the activities associated with production capabilities of (b) (4) that allow for a consistent quality supply of FDA compliant devices during 2021 to meet the project goals as outlined in this proposal. The activities are divided into two categories: 1. activities required for FDA compliant manufacturing (including testing, QA, and equivalency testing), and 2. manufacturing activities to build up production capacity. Although both categories are presented below, all activities associated with scaling manufacturing are listed as *out of scope* for this project.

4.1. **Facility setup I** - FDA compliant production capability is divided into two phases, and this is the first. The initial work will be focused on Automated End of Line testing, featuring machinery necessary to perform the first finalized production build starting in Q4. Relevant machinery will be the setup on End of Line testing machines featuring flying probes, for the test of complex electronic boards, and automated calibration.

4.2. **Testing procedures** - The team will work to implement testing procedures to support manufacturing builds, based on the machinery acquired in the facility setup milestone.

4.3. **Facility setup II** - This milestone will include the bulk of the machinery required to set up production for the (b) (4). For the sake of the project, only activities required by regulatory compliance are considered here: included are automated assembly, testing, and calibration machines for final testing. Approval of this milestone and the subsequent ones are performed by the company with relevant status reports available.

4.4. **Production Validation Build and Testing (out of scope)** - Empatica is already (b) (4)

(b) (4)

4.5. (b) (4)

4.6. (b) (4)

4.4. (b) (4)

5. ***Online clinical trial for 300 target users*** - These milestones cover the work required for successful validation of Empatica's final product, including (b) (4) (Product Packages 1, 2 and 3 from Milestone 3) and the (b) (4). Empatica will set up and run an online trial through an IDE, in parallel to the filing of the 510(k) clearance of the Aura system on (b) (4).

5.1. **Clinical trial setup** - The team will prepare all the preliminary steps to launch the study, as it has successfully done in the past. It will manufacture (b) (4) in the FDA compliant facility, set up the account management and recruitment. The outcome is the start of the study.

5.2. **Last patient out** - Last patient out of the study will close the data collection phase.

5.3. **Data processing** - The team will perform analysis of the data collected during the study. The outcome of this milestone is the clinical study report on the performance and compliance of the users.

Deliverables

Milestone #	Milestone	Deliverable
1	***Clinical trial 150 healthy patients***	
1.1	Clinical trial setup	First patient enrolled
1.2	Last patient out	DB lock
1.3	Data processing	Performance analysis document
2	***Regulatory filings (out of scope)***	
-	*EUA status (out of scope)*	
-	*DeNovo filing (out of scope)*	
3	***Platform testing and service integration***	
3.1	Testing Product Package 3	Release notes and testing report for Product Package 3
3.2	Testing Product Package 2	Release notes and testing report for Product Package 2
3.3	Testing Product Package 1 v1	Release notes and testing report for Product Package using E4 device
3.4	Testing Product Package 1 v2	Release notes and testing report for Product Package using EmbracePlus
4	***EmbracePlus manufacturing setup***	
4.1	Facility setup I	Status report on initial setup for FDA compliant manufacturing
4.2	Testing procedures	Test report on implemented test procedures
4.3	Facility setup II	Status report on final setup for FDA compliant manufacturing
-	*Production PV Build and Testing (out of scope)*	
-	*Tooling (out of scope)*	
-	*Production MP Build and Testing (out of scope)*	
4.4	Final Quality Assurance and Testing validation	Status report on FDA Compliance setup following final first production build
5	***IDE trial on 300 healthy consumers***	

	pre-launch	
5.1	Clinical trial setup	First patient enrolled
5.2	Last patient out	DB lock
5.3	Data Processing	IDE trial results report

Milestone Payment Schedule

MTEC Milestone Number	Task Number	Significant Event/ Accomplishments	Due Date	Government Funds	Cost Share	Total Funding
1	1.2	First patient in (enrolled)	9/2/2020	$(b) (4)	(b) (4)	(b) (4)
2	4.1	Status report on initial setup for increased production capacity	9/2/2020	$(b) (4)	(b) (4)	(b) (4)
3	3.1	Release notes and testing report for Product Package 3	9/30/2020	$(b) (4)	(b) (4)	(b) (4)
4	4.2	Test report on implemented test procedures	10/14/2020	$(b) (4)	(b) (4)	(b) (4)
5	-	Bimonthly report 1	10/14/2020	$(b) (4)	$(b) (4)	$(b) (4)
6	1.2	DB lock	10/21/2020	$(b) (4)	(b) (4)	(b) (4)
7	3.2	Release notes and testing report for Product Package 2	10/28/2020	$(b) (4)	(b) (4)	(b) (4)
8	3.3	Release notes and testing report for Product Package using E4 device	10/28/2020	$(b) (4)	(b) (4)	(b) (4)
9	1.3	Data processing completed	11/4/2020	$(b) (4)	(b) (4)	(b) (4)
10	-	Bimonthly report 2	12/16/2020	$(b) (4)	$(b) (4)	$(b) (4)
11	4.3	Status report on final setup for increased production capacity	12/23/2020	$(b) (4)	(b) (4)	(b) (4)
12	5.1	First patient enrolled	12/30/2020	$(b) (4)	(b) (4)	(b) (4)
13	3.4	Release notes and testing report for Product Package using EmbracePlus	1/27/2021	$(b) (4)	(b) (4)	(b) (4)
14	-	Bimonthly report 3	2/17/2021	$(b) (4)	$(b) (4)	$(b) (4)
15	4.4	Status report on FDA Compliance setup following final first production build	2/24/2021	$(b) (4)	(b) (4)	(b) (4)
16	5.2	DB lock	3/3/2021	$(b) (4)	(b) (4)	(b) (4)
17	5.3	IDE trial results report	3/24/2021	$(b) (4)	(b) (4)	(b) (4)
18	-	Final Reports (Business and Technical)	3/31/2021	$(b) (4)	$(b) (4)	$(b) (4)
		TOTAL		$(b) (4)	(b) (4)	$3,576,434.00

Shipping Provisions

The shipping address is:

Empatica Inc, (b) (4) [redacted]

Reporting

Bimonthly Reports – The MTEC research project awardee shall prepare a Bimonthly Report which will include a Technical Status Report and a Business Status Report in accordance with the terms and conditions of the Base Agreement. (Required)

Final Technical Report – At the completion of the Research Project Award, the awardee will submit a Final Technical Report, which will provide a comprehensive, cumulative, and substantive summary of the progress and significant accomplishments achieved during the total period of the Project effort in accordance with the terms and conditions of the Base Agreement. (Required)

Final Business Status Report – At the completion of the Research Project Award, the awardee will submit a Final Business Status Report, which will provide summarized details of the resource status of the Research Project Award, in accordance with the terms and conditions of the Base Agreement. (Required)