



**DEPARTMENT OF THE ARMY
U.S. ARMY CONTRACTING COMMAND – NEW JERSEY
PICATINNY ARSENAL, NEW JERSEY 07806-5000**

REPLY TO
ATTENTION OF

21 July 2020

Army Contracting Command – New Jersey
ACC-NJ, Building 9
Picatinny Arsenal, NJ 07806

SUBJECT: Technical Direction Letter for Medical CRBN Defense Consortium (MCDC), Request for Prototype Proposals (RPP) 20-11, Objective PRE-20-11 for “COVID-19 Pandemic – Large Scale Vaccine Manufacturing Demonstration” (Pfizer, Inc.)

REF: Prizer Request for Technical Direction Letter, RPP 20-11 under OTA W15QKN-16-9-1002 for Objective PRE-20-11, dated 20 July 2020

Advanced Technology International
ATTN: (b) (6), Sr. Contracts Manager
315 Sigma Drive
Summerville, SC 29486

Dear (b) (6),

The Army Contracting Command – New Jersey (ACC-NJ), in supporting the Joint Project Manager – Medical Countermeasure Systems (JPM-MCS), issued MCDC RPP 20-11 on 09 June 2020. Members of the MCDC submitted proposals in accordance with this RPP. The Government received and evaluated all proposal(s) submitted and a Basis of Selection has been executed, selecting Pfizer, Inc. as the awardee. The Government requests that a Firm-Fixed-Price Project Agreement be issued to Pfizer, Inc. to award this proposal under Other Transaction Agreement W15QKN-16-9-1002, to be performed in accordance with the attached Government Statement of Work (SOW).

Based upon the acceptable update of Pfizer, Inc.’s proposal for “COVID-19 Pandemic – Large Scale Vaccine Manufacturing Demonstration” and 1) The Project Agreement Recipient’s concurrence with the requirements included in the Government SOW; 2) An acceptable milestone schedule that meets SOW requirements, and; 3) The price proposed that has been analyzed by the Government, you are hereby directed to issue a Project Agreement to Pfizer, Inc. for the subject project. The total project value has been determined fair and reasonable and Pfizer, Inc.’s proposal has been selected IAW the above referenced Basis of Selection.

The total approved cost to the Government for this effort is not to exceed \$1,950,097,500.00. The break-out of the costs is as follows: \$1,950,000,000.00 to perform project efforts included in the SOW and \$97,500.00 for the Consortium Management Firm (CMF) Administrative Cost. The CMF Administrative Cost was approved as a “Special Allocation” for Operation Warp Speed (OWS) Prototype Projects executed under the MCDC OTA. The effort currently has \$1,950,097,500.00 of available funding, comprised of \$1,950,000,000.00 for the Project Agreement, \$67,500.00 for the CMF Special Allocation, and \$30,000 for other, non G&A, ATI costs, which will be incurred, tracked,

and invoiced in accordance with Article V of the OTA. The COVID-19 work shall be tracked separately using the funding obligated via modification P00076. In alignment with the special allocation conditions, it is noted that this project has a base period of performance (b) (4), with a projected completion date of (b) (4). A customized clause for the special allocation, will be incorporated into the funding modification for this prototype project.

The prime contractor is considered a small business, nontraditional defense contractor, or nonprofit research institution and determined to be providing a significant contribution. The affirmation of business status certifications submitted as part of the proposal are hereby incorporated into the agreement. The contractor shall notify the MCDC CMF of any deviation from the final proposed affirmation of business status certifications that would affect the contributions of the small business, nontraditional defense contractor, or nonprofit research institution as proposed.

In accordance with 10.U.S.C. 2371b(f), and upon a determination that the prototype project for this transaction has been successfully completed, this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction without the use of competitive procedures.

Points of Contact:

Agreements Specialist:

(b) (6)

E-mail: (b) (6)

Phone: (b) (6)

Agreements Officer:

(b) (6)

E-mail: (b) (6)

Phone: (b) (6)

Regards,

X (b) (6)

(b) (6)

Agreements Officer

Signed by: (b) (6)

Attachments:

Attachment 1: MCDC2011-003 – Pfizer - 7-21-2020

Attachment 2: SOW Appendix 1 Clause for MCDC Consortium Other Transaction Authority Agreements

**Statement of Work
For
COVID-19 PANDEMIC--LARGE SCALE VACCINE MANUFACTURING
DEMONSTRATION**

RPP #: 20-11

Project Identifier: 2011-003

Consortium Member: Member

Title of Proposal: COVID-19 Pandemic--Large Scale Vaccine Manufacturing Demonstration
Requiring Activity: Joint mission between the Department of Health and Human Services and Department of Defense to combat COVID-19

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

1.1 Introduction

This Statement of Work (the “Statement of Work”) is hereby entered into, effective as of July 21, 2020, pursuant to that certain Project Agreement by and between MCDC and Pfizer dated as of July 21, 2020 (“this Agreement” or “Project Agreement”).

An outbreak of respiratory disease caused by a novel coronavirus was first detected in China in late 2019 and has now spread worldwide, including the United States (“US”). The virus has been named Severe Acute Respiratory Disease Coronavirus-2 (“SARS-CoV-2”) and causes Coronavirus Disease 2019 (“COVID-19”). On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (“WHO”), declared the outbreak a “Public Health Emergency of International Concern”. On January 31, the US Department of Health and Human Services Secretary (“HHS”), Alex M. Azar II, declared a Public Health Emergency for the US to aid the nation’s healthcare community in responding to COVID-19. On March 11, 2020, WHO publicly characterized COVID-19 as a pandemic. On March 13, 2020 the President of the United States declared the COVID-19 outbreak a national emergency. The Government has identified COVID-19 vaccine candidates that are progressing rapidly through advanced research and development activities.

Therefore, in response to a request by the Government, Pfizer is proposing to manufacture at-scale and fill-finish, for provision to the Government, a state-of-the-art candidate vaccine, developed in collaboration with BioNTech and capable of providing protection against the SARS-CoV-2 threat and related coronaviruses, subject to technical, clinical and regulatory success.

Pfizer and BioNTech’s program aims to revolutionize the vaccine field by providing an mRNA candidate that, itself, has several key advantages, including the efficiency and flexibility of the platform – which is apparent by the pace of the vaccine development and the unprecedented phase

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1/2/3 trial design that it supports. A clear fundamental difference of this candidate over more traditional modalities, such as viral vector vaccines, is that mRNA is delivered by protein-free lipid nanoparticles, which is believed to abolish the risk of anti-vector immunity and permit boosting to maximize the level and duration of immune responses.

The mRNA vaccine technology is also intended to enable quick scale up of production, which is critical for bringing a COVID-19 vaccine to market to address this urgent medical need while preserving high quality and safety standards.

The intent of this prototype project is to demonstrate that Pfizer has the business and logistics capability to manufacture 100M doses of its currently unapproved mRNA-based COVID-19 vaccine for the Government (b) (4), using the Pfizer/BioNTech unique mRNA delivery system and its associated cold chain requirements, under pandemic conditions. This prototype project aims to significantly accelerate and secure US access to this promising medical countermeasure based on domestic manufacturing.

1.1.1 BACKGROUND

(b) (4), Pfizer and BioNTech entered into an agreement for the co-development and distribution (excluding China) of a potential mRNA-based coronavirus vaccine aimed at preventing COVID-19 infection (the "Pfizer/BioNTech Agreement"). Under the Pfizer/BioNTech Agreement, (b) (4)

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(b) (4)

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(b) (4)

The collaboration has rapidly advanced multiple COVID-19 vaccine candidates into human clinical testing based on BioNTech's proprietary mRNA vaccine platforms, with the objective of ensuring rapid worldwide access to the vaccine, if approved. The collaboration leverages Pfizer's broad expertise in vaccine research and development, regulatory capabilities, and global manufacturing and distribution network. The two companies are jointly conducting clinical trials, and will also work jointly to commercialize the vaccine upon regulatory approval.

Pfizer and BioNTech have already made substantial progress, outside this Statement of Work and without use of any Government funding, towards the demonstration of technical and manufacturing feasibility, including through the initiation of Phase 1/2 studies evaluating the likelihood of safety, tolerability and immunogenicity in the US and in Germany. The goal of the program is to rapidly develop and obtain regulatory licensure for a vaccine for use in adults ≥ 18 years of age, followed by a possible pediatric and/ or maternal indication (to protect ~4M US pregnant women at risk each year). Both companies aspire to have an FDA-approved or authorized vaccine ready for administration in the US by October 31, 2020. Based on current information, Pfizer and BioNTech anticipate a 2-dose per patient regimen.

This Statement of Work is designed toward establishing production capacity and distribution infrastructure sufficient to ensure that doses of the vaccine manufactured under this Agreement can be made available immediately for administration in the US, if clinical trials are successful and the FDA grants an Emergency Use Authorization ("EUA") under Section 564 of the Federal Food, Drug, and Cosmetic Act or Biologics License Application ("BLA") licensure under Section 351(a) of the Public Health Service Act (hereafter "FDA-approved or authorized").

1.1.2 ACTIVITIES UNDERTAKEN WITHOUT GOVERNMENT FUNDING

This section describes activities that Pfizer and BioNTech have been performing and will continue to perform without use of Government funding. These activities are described solely for background and context for the Government-funded deliverables itemized in Section 4.

A. Regulatory Planning

Pfizer will meet the necessary FDA requirements for conducting ongoing and planned clinical trials, and with its collaboration partner, BioNTech, will seek FDA approval or authorization for the vaccine, assuming the clinical data supports such application for approval or authorization. Given that these clinical trials are regulated by the FDA and HHS, there is no need for separate regulation by the U.S. Army Medical Research and Materiel Command. BioNTech is the Investigational New Drug ("IND") holder, while Pfizer is the designated agent for all interactions with the FDA and is taking the lead on all communications with and submissions to FDA.

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B. Clinical and Regulatory Approach

BioNTech is the regulatory sponsor for trials of the vaccine and will be the applicant in the US for an EUA and/or a BLA, and will ultimately be the holder of any such approval issued in the US. Pfizer is BioNTech's authorized agent to FDA. As noted above, Pfizer is the designated agent for all interactions with the FDA and is taking the lead on all communications with and submissions to FDA.

Prior to commencing clinical development, on February 6, 2020, BioNTech obtained feedback from the Paul Ehrlich Institute ("PEI") on plans for rapid vaccine development in response to the COVID-19 outbreak following a Scientific Advice Meeting. Based on the PEI feedback, BioNTech refined the clinical program plan and prepared a detailed protocol for FIH clinical study (BNT162). Additionally, a meeting was held by BioNTech on February 24, 2020 with the Chinese CDC to discuss a possible Special Review Procedure.

In Germany, BioNTech began a Phase 1/2 study (BNT162-01) in late April 2020. BNT162-01 is a dose-escalation trial investigating the safety and immunogenicity of COVID-19 mRNA vaccine candidates in healthy adults. The primary objective of the study is to describe the safety and tolerability profiles of prophylactic BNT162 vaccine candidates after a single dose (for saRNA) or two doses separated by 21 days (uRNA and modRNA candidates). The secondary objective of the study is to describe the immune response to the vaccine in healthy adults, as measured by a functional antibody assay, such as virus neutralization.

Informed by BNT162-01, the Phase 1/2 US study (C4591001) of the vaccine candidates started in May 2020. Pfizer and BioNTech utilized this approach to efficiently optimize formulation and dose selection in the clinic. Study C4591001 is a single, multistage and multi-phase trial (including the pivotal efficacy portion) designed to generate the data needed to achieve FDA approval or authorization for use of one of the vaccine candidates. This is a randomized, placebo-controlled, observer-blind, dose-finding and vaccine candidate-selection study in healthy adults. The study is evaluating the safety, tolerability, and immunogenicity of the COVID-19 mRNA vaccine candidates.

The study consists of 3 stages:

Stage 1: to identify preferred vaccine candidate(s), dose level(s), number of doses, and schedule of administration (with the first 15 participants at each dose level of each vaccine candidate comprising a sentinel cohort);

Stage 2: an expanded-cohort stage; and

Stage 3: a final candidate/dose large-scale stage.

Using this approach, Pfizer and BioNTech are efficiently working towards selection of final candidate/dose level.

The study currently is being amended to incorporate a pivotal efficacy study design. Therefore, the study would be converted to a single Phase 1/2/3 study. The pivotal study portion (*i.e.*, Phase 2b/3) is expected to enroll up to ~30,000 subjects (1:1 randomized between vaccine and placebo).

Upon gathering adequate safety and immunogenicity/efficacy data in a sufficient number of subjects, Pfizer believes the vaccine candidate could, with FDA’s agreement, be administered under EUA.

As background, Pfizer’s and BioNTech’s activities to ensure provision of vaccine on a timely schedule may include the following discrete activities, depending on emerging data and regulatory guidance.

Activity	Success Criteria	Estimated Timing
Candidate, dose, and regimen selection	Decision endorsed by Pfizer-BioNTech Joint Steering Committee	(b) (4)
Phase 2b/3 Study Start	Requires FDA (CBER) approval	(b) (4)
Phase 1/2/3 Demonstration of immunogenicity, efficacy (interim analysis) and safety	Adequate efficacy and safety data supports EUA application	(b) (4)
EUA Submission to Support Use in American Population	Acceptance of EUA submission	(b) (4)
BLA Submission to Support Use in American Population	Agreement from FDA (CBER) that proposed licensure package (preclinical, clinical, CMC) is acceptable	(b) (4)
EUA Issuance to Support Use in American Population	EUA issued	(b) (4)
BLA Approval to Support Use in American Population	BLA approval	(b) (4)
Post-Approval Commitments Agreed	Agreement with FDA	(b) (4)

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C. Chemistry Manufacturing Controls (CMC)

Pfizer will complete the necessary CMC and scale-up activities to demonstrate the ability to manufacture 100M doses (b) (4). Pfizer will use diligent efforts to manufacture and quality release (using Pfizer's quality system) 100M doses within the US in a non-preservative multi-dose vial (b) (4).

Pfizer currently estimates potential production rates (b) (4). With GMP production expected to commence (b) (4) for drug product, this plan would allow for ~40M doses to be supplied under this Statement of Work in (b) (4). As Pfizer validates the facilities and makes continuous process improvements, Pfizer currently anticipates such production rate to increase starting in (b) (4). Should clinical data indicate that a lesser amount of dosage may be needed, there could be an increase in the anticipated potential number of doses supplied in (b) (4).

As background, to help ensure delivery of the doses, Pfizer is undertaking the following CMC activities:

1. Continue with BioNTech to manufacture initial clinical trial material for EU and US Phase 1/2/3 studies, through mRNA production in Germany and EU (Puurs, Belgium for fill-finish) and drug product/labelling operations at EU CMOs and establish EU based supply chain for lipid nanoparticle (LNP) formulation, fill, finish and distribution for commercial supply.

2. Complete knowledge transfer of the technology and manufacturing process from BioNTech (and its CMO partners) to Pfizer in order to establish the process at Pfizer in the US, (b) (4)

3. Obtain all raw material supplies for manufacturing. This may include support of existing third-party suppliers of raw materials, qualifying new third-party suppliers and/or in-house production of certain raw materials, (b) (4)

4. Establish (b) (4) mRNA (drug substance), lipid nanoparticle (LNP) formulation/fill finish (drug product) capacity for GMP Covid-19 pandemic supply of the RNA-based COVID-19 vaccine on US soil.

5. Develop the shipping model for the -80 °C drug product in consultation with CDC.

In parallel, Pfizer is prepared to also evaluate alternative options including:

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1. Conduct necessary stability and development studies to establish (b) (4)

2. Conduct necessary formulation and stability studies to develop (b) (4)

The CMC program may include, but not be limited to: (a) (b) (4); (b) drug substance development; (c) drug product development (LNP formulation, fill-finish); (d) analytical development in GLP and GMP setting; (e) GLP and GMP manufacturing; and (f) and shipping of -80 °C frozen product.

(a) (b) (4)

(b) Drug Substance Development: Pfizer shall scale-up its capabilities for process optimization, manufacture, analysis, release of GMP materials (mRNA) and securing necessary raw materials from third party providers. For drug substance manufacture, Pfizer seeks to build-out the existing purification suite located at Pfizer's (b) (4)

Pfizer shall supply incremental resources to transfer/implement new technology and GMP manufacturing processes, including technical experts, quality professionals, analytical technicians, and trained operational staff.

(c) Drug Product Development (Lipid Nanoparticle (LNP Formulation, Fill-Finish)): Activities Pfizer shall perform may include, but are not be limited to, securing of necessary lipids for formulation and manufacturing process development for BNT162; defining the formulation; and initial development of manufacturing process and analytical methods. Pfizer will undertake to (b) (4)

(d) Analytical Development: Analytical development may include, but not be limited to: methods transfer participation at receiving site and in-process testing support; process verification on commercial equipment; media fill runs; engineering trials; registration batch manufacture; and registration batch stability (pivotal stability) testing. (b) (4)

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(e) GLP and GMP Manufacturing: Packaging, storage and distribution of clinical trial supplies for Phase 1/2 will be conducted by (b) (4)

(f) Shipping of -80 °C frozen product: Pfizer is evaluating extension of current clinical packaging configuration using soft boxes and dry ice. (b) (4)

As background, to maintain a timely completion schedule of the vaccine, Pfizer is aspiring to undertake the following discrete activities, without Government funding:

(b) (4)

1.2 Scope

The scope of this prototype project is the demonstration by Pfizer of the supply and logistics capability to manufacture and distribute to the Government of 100M doses of a novel mRNA-based vaccine that has received FDA-approval or authorization based on demonstration of efficacy (hereafter FDA-approved or authorized). The criteria for successful Emergency Use Authorization (EUA) are described in *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders, January 2017*; and *Development and Licensure of Vaccine to Prevent COVID-19: Guidance for Industry June 2020*. The successful provision of these doses shall establish the effectiveness of a technology capable of potentially providing immediate and long-term solutions to coronavirus infections. While pre-clinical, clinical, and chemistry/manufacturing/controls (CMC) activities are described in the Background section of this Statement of Work, the Parties acknowledge and agree that such activities not related to the large-scale manufacturing demonstration are out-of-scope for this prototype project as Pfizer and BioNTech have and will continue to fund these activities, without the use of Government funding.

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1.3 Objective

(a) Prototype Project

As set forth more fully in Section 11.7, the provisions of this Section 1.3 hereby supersede and replace, in their entirety, the provisions of Section 21.15 of the MCDC Base Agreement, 2020-532 (July 2018) (“Base Agreement”).

Consistent with the Government’s objectives under Operation Warp Speed, Pfizer intends to employ its proprietary manufacturing technology and processes, in a manner compliant with applicable laws and regulations, including 21 CFR 210 and 211 and the Drug Supply Chain Security Act (to the extent required for COVID-19 medical countermeasures, as defined by relevant FDA guidance), to manufacture and deliver vaccine. Success of the prototype project is defined as manufacture of 100M doses of Pfizer and BioNTech’s mRNA-based COVID-19 vaccine and, upon FDA-approval or authorization as described above, delivery of those doses in accordance with Section 6.0.

This effort constitutes a prototype project because it will be used to evaluate the technical feasibility of completion of the prototype project during the ongoing COVID-19 pandemic and unprecedented threats to several components of the prototype project. In addition, this is a prototype project because Pfizer will demonstrate and prove-out the at-scale, multi-lot proprietary manufacturing activities in order to assess the feasibility to support the necessary quantity of safe and effective doses required for vaccination of the U.S. population and deliver those doses within challenging cold chain requirements in accordance with Section 6.0. Successful completion of the prototype project will demonstrate Pfizer’s capability to (i) rapidly manufacture product, which can be further scaled-up to meet mutually agreed to surge requirements with limited advance notification and (ii) distribute large quantities of the FDA-approved or authorized drug product in accordance with Section 6.0. For clarity, any manufacturing and delivery of drug product in excess of the specific quantities set forth in Section 4.0 of this Statement of Work, shall be subject to a separate mutually acceptable production agreement between Pfizer and the Government.

(b) Follow-On Production Contract/Options

In accordance with 10.U.S.C. § 2371b(f), and upon a determination that the prototype project is successful, or at the accomplishment of particularly favorable or unexpected results that would justify transition to production, the Government and Pfizer may enter into a non-competitive, mutually-acceptable, follow-on production agreement for additional manufacturing of the vaccine without the use of competitive procedures, which agreement shall reflect an unfunded option on the basis set forth in the following paragraph (the “Option”).

Under the Option, the Government may request that Pfizer produce and deliver up to 500M additional doses for purchase by the Government for delivery (b) (4)

Any order placed pursuant to the Option Agreement will provide for a

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minimum of 100M doses, provided that the aggregate number of doses ordered under the Option shall not exceed 500M.

Upon any request pursuant to the Option, Pfizer shall inform the Government of appropriate lead times based on purchase of raw materials, capacity reservation and other factors, and Pfizer and the Government shall mutually agree on an appropriate estimated delivery schedule. Each order under the Option will be subject to the reasonable acceptance of Pfizer, it being understood that Pfizer shall have no obligation to accept any order pursuant to the Option that would involve (b) (4)

As promptly as practicable following the effective date of this Agreement, the Government and Pfizer will agree in principle upon a form of production agreement reflecting the Option that can be executed as a binding agreement promptly upon Government request following such determination, demonstration, or accomplishment.

2.0 APPLICABLE REFERENCES

Current Good Manufacturing Procedures, 21 CFR 210 and 211.

3.0 REQUIREMENTS

Pfizer shall conduct manufacturing activities to support production and distribution of vaccine doses after the final vaccine candidate from its development program is selected (currently expected to occur in July 2020). Subject to the terms and conditions of this Agreement, including without limitation Sections 3.1, 6.0, 11.5 and 11.6, Pfizer shall use diligent efforts to manufacture, quality release (using Pfizer's quality system), and deliver 100M doses of an FDA-approved or authorized vaccine in a preservative-free, multi-dose vial no later than the end of the period of performance (as defined in Section 3.1).

Pfizer anticipates providing the vaccine, subject to FDA approval or authorization, as -80 °C frozen product that needs to be maintained at or below that temperature prior to dosing. The Government acknowledges that Pfizer's responsibility for cold chain will cease upon delivery in accordance with Section 6.0.

Pfizer anticipates providing the vaccine, subject to FDA-approval or authorization, as a concentrate that needs to be diluted at point of use prior to dosing. Vaccinators will need to use locally sourced 0.9% Sodium Chloride Injection, USP (Normal Saline), syringes and needles.

3.1 Period of Performance

The total proposed duration of this prototype initiative is (b) (4) with an expected completion date (b) (4) (the "period of performance"). If FDA-approval or authorization is not issued by October 31, 2020

as estimated in Section 1.1.2 above, and Pfizer expects it will be unable to timely complete performance, then the Parties will discuss in good faith a contract modification to shift forward the estimated delivery schedule to reflect the difference in time period between October 31, 2020 and the date of actual regulatory approval or authorization.

As a result of these discussions, the Government shall have the unilateral ability to extend the Period of Performance of this prototype project in increments of up to thirty (30) days at a time. In no event can this unilateral right to extend the period of performance require performance (b) (4) or result in a requirement for Pfizer to demonstrate the ability to manufacture more than 100M doses.

Notwithstanding the efforts and estimated dates set forth throughout this Statement of Work, and as set out more fully in Sections 11.5 and 11.6, both Parties recognize that the vaccine is currently in Phase 1/2 clinical trials and that, despite the diligent efforts of Pfizer and BioNTech in research, and development and manufacturing, the prototype project may not be successful due to technical, clinical, regulatory or manufacturing challenges or failures.

3.2 Management and Reporting

As set forth more fully in Section 11.7, the provisions of this Section 3.2 hereby supersede and replace, in their entirety, Section 1.05 of the Base Agreement.

Pfizer will not employ any new or other Project Management components and Pfizer shall have no obligation to provide any custom reports to the Government except as provided herein. The Government acknowledges that Pfizer plans to utilize existing Pfizer-formatted reports to provide this information to the Government as described in the Deliverable table below at Section 4.0.

Pfizer shall provide (b) (4) technical reports providing an update of relevant ongoing non-Government funded activities.

Pfizer shall provide, (b) (4) a synopsis of the Phase 2b/3 clinical trial protocol, which synopsis shall include [Overview of the Protocol, Objectives and Endpoints, Statistical Methods, and Schedule of Activities].

Pfizer shall provide copies of EUA and BLA filings, as well as interim and final data updates from clinical studies in a format determined by Pfizer.

Pfizer shall provide weekly prototype production status reports, including the number of batches produced, doses in the batch, and release status of the finished doses.

In addition to regular reporting requirements, during the period of performance, Pfizer shall use diligent efforts to notify the Government (b) (4) of any event, risk, formal or informal

FDA communication, or other issue that would be reasonably expected to materially change the anticipated schedule by one week or more.

Except for reports expressly contemplated in this Statement of Work, Pfizer and the Government agree that Pfizer will not be subject to any reporting requirements contemplated in Section 1.05 of the Base Agreement.

4.0 DELIVERABLES

As set forth more fully in Sections 11.5 and 11.6, the Government understands that the dates set forth below are Pfizer’s best estimate, as of the Execution Date of this Agreement, of its development and manufacturing timelines, and that these timeframes are subject to significant risks and uncertainties. Pfizer will promptly notify the Government of any event(s) that would be reasonably expected to materially alter projected Estimated Due Date for Deliverables 4.1 through 4.20.

The Government agrees that it will not resell any of the deliverables to any third party.

Deliverables

Del. #	Deliverable Description	Estimated Due Date	Format	SOW Reference	Government Role	Data Rights
4.1	Project Kick-Off materials	(b) (4)	Telecon. and related slides	--	Review	(b) (4)
4.2	Phase 2b/3 Clinical Trial Synopsis	(b) (4)	Pfizer-determined format	(b) (4)	Review	(b) (4)
4.3	Provision of PL 115-92 Sponsor Authorization Letter	(b) (4)	--	--	Review/ Approve	(b) (4)
4.4	(b) (4) Updates on Prototype Production Status	(b) (4)	Pfizer-determined format	(b) (4)	Review	(b) (4)
4.5	(b) (4) Business and Technical Report	(b) (4)	Pfizer-determined format	(b) (4)	Review	(b) (4)

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4.6	EUA Filing	(b) (4)	Pfizer-determined format	(b) (4)	Review	(b) (4)
4.7	BLA Filing	(b) (4)	Pfizer-determined format	(b) (4)	Review	(b) (4)
4.8	Delivery of 100M doses	(b) (4)	--	(b) (4)	Receipt	(b) (4)
4.9	Release documentation for delivered doses	(b) (4)	Pfizer-determined format	(b) (4)	Review	(b) (4)
4.10	Supply Chain Resiliency Plan or Pfizer Equivalent	(b) (4)	Pfizer-determined format	(b) (4)	Review & Comment	(b) (4)
4.11	Manufacturing Data Requirement or Pfizer Equivalent	(b) (4)	Pfizer - determined format	(b) (4)	Review & Comment	(b) (4)
4.12	Product Development Source Material & Manufacturing Reports and Projections	(b) (4)	Pfizer-determined format	(b) (4)	Review & Comment	(b) (4)
4.13	Work Location Report or Pfizer Equivalent	(b) (4)	Pfizer-determined format	(b) (4)	Review & Comment	(b) (4)
4.14	Facility Security Plan or Pfizer Equivalent	(b) (4)	Pfizer-determined format	(b) (4)	Review & Comment	(b) (4)
4.15	Confirmation of Registration and Listing with FDA	(b) (4)		(b) (4)	Review	(b) (4)

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4.16	Formal Written Responses from the FDA	(b) (4)		(b) (4)	Review	(b) (4)
4.17	FDA Inspection and Compliance Notices, Observations and Responses	(b) (4)		(b) (4)	Review	(b) (4)
4.18	Manufacturing Development Plan*	(b) (4)		(b) (4)	Review	(b) (4)
4.19	Quality Management Plan**	(b) (4)		(b) (4)	Review	(b) (4)
4.20	Shipping Specifications and Details	(b) (4)		(b) (4)	Review	(b) (4)

* Manufacturing Development Plan. Pfizer will, (b) (4) describe the manufacturing process for the vaccine product to ensure conformity with §501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21 United States Code (“U.S.C.”) §351 (a)(2)(B)), regarding good manufacturing practices (“GMP”). This plan shall describe (b) (4)

** Quality Management Plan. Pfizer will, (b) (4) provide a quality management plan (b) (4)

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The Government acknowledges that, as set forth more fully in Section 1.1.2, the above deliverables (other than the delivery of doses contemplated by Section 4.5) are being prepared without the use of Government funding.

As used herein, the term “Limited” means “limited rights” as that term is defined in DFARS 252.227.7013(a)(14).

5.0 MILESTONE PAYMENT SCHEDULE

As set forth more fully in Section 11.7, the provisions of this Section 5 supersede and replace, in their entirety, the provisions of 5.04b of the Base Agreement.

As the clinical trials and validation of the product presentation are ongoing, the estimated timing of delivery of doses is subject to change. Provided the FDA has granted approval or authorization, the 100M doses will be provided by Pfizer to the Government on a Firm Fixed Price per dose basis in accordance with the Milestone Payment Schedule. Due to variances in fill/finish yield, Pfizer shall invoice for and the Government, through the Consortium Management Firm (CMF), shall pay for actual quantities delivered, at a rate of \$19.50 per dose. Subject to regulatory and technical success, Pfizer shall use its diligent efforts to provide the Government the full 100M doses on or before the final delivery date.

Upon release, Pfizer will ship the doses to the Government as set forth in Section 6.0, below. Pfizer expects to invoice the Government (through the CMF) every month for released doses that have been shipped during each such monthly period. The CMF will pay all such invoices within thirty (30) days of receipt thereof. Pfizer shall submit invoices via email to MCDC-invoices@ati.org.

(b) (4)

Total (Include Payment Type; FFP):		\$1.95B
(b) (4)		

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Except as contemplated by the Option, the price per dose set forth in this Statement of Work is provided in connection with Operation Warp Speed and this specific Statement of Work only. This price shall not serve as the basis for pricing under any separate government contracts between Pfizer and HHS, the Department of Defense, or any other Department or agency of the Government by application of most favored customer, most favored nations, or any other contract or program-specific terms.

For clarity, the Government will have no right to withhold payment in respect of any delivered doses, unless the FDA has withdrawn approval or authorization of the vaccine. In such event, the Parties will work in good faith to establish an appropriate course of action for delivered doses which have not yet been administered. By way of illustrative example only, (b) (4)

[REDACTED]

6.0 SHIPPING PROVISIONS

In coordination with the Government, Pfizer will conduct a demonstration of the shipping process prior to the first delivery of doses at a time mutually agreed by the Parties. As set forth in Section 4.0, Pfizer agrees to share specifications and details associated with the shipping process and containers to enable the Government to adequately plan and prepare for potential distribution of the vaccine.

Pfizer will notify the Government the date by which doses will become available for delivery. The Government will confirm dosage orders by ship-to location (b) (4) in advance of those dates; *provided* that each such ship-to location will abide by the specifications provided by Pfizer or will otherwise be agreed by Pfizer and the Government. The number of ship-to locations and the manner of delivery shall be identified to create an efficient delivery of the doses, subject to mutual agreement of the parties. The recommended delivery quantity for each ship-to location is (b) (4)

[REDACTED]

(b) (4)

7.0 INTELLECTUAL PROPERTY, DATA RIGHTS, AND COPYRIGHTS

As set forth more fully in Section 11.7, the provisions of this Section 7.0 supersede and replace, in their entirety, the provisions of Article X (Patent Rights), Article XI (Data Rights) of the Base Agreement.

7.1 Inventions

As between Pfizer and the Government, Pfizer shall hereby retain all of its rights, titles and interests in and to any and all inventions conceived and reduced to practice by Pfizer and/or BioNTech (i) as of the Effective Date of this Agreement, or (ii) after the Effective Date of this Agreement, outside the scope of this Statement of Work (“Background Inventions”). Pfizer does not grant to the Government any license to practice the Background Inventions under this Agreement.

As between Pfizer and the Government, all inventions conceived or first actually reduced to practice in the performance of this Statement of Work (“Subject Inventions”) shall be owned by Pfizer. If invented solely by Pfizer, Pfizer will be able to elect, in its discretion, whether to hold Subject Inventions as trade secrets, and holding a Subject Invention as a trade secret will not forfeit title to the Government. Pfizer does not grant to the Government a license to practice any Subject Inventions on behalf of the Government.

Notwithstanding the foregoing, and as set forth more fully in Section 1.1.2, the Government acknowledges that it is not funding the research or development of the vaccine, or CMC/process development in respect thereof. As such, neither Pfizer nor the Government anticipate the conception or reduction to practice of any Subject Inventions.

The Government acknowledges that the Bayh-Dole Act does not apply to or govern this Agreement. Given that the Government will not fund the conception or reduction to practice of Background Inventions or Subject Inventions hereunder, this Agreement shall neither (i) give the Government any rights to “march-in,” as that term is defined in 35 U.S.C. § 203, nor (ii) subject Pfizer to the manufacturing requirements of 35 U.S.C. § 204.

7.2 Data

The Government recognizes that all data relating to the vaccine has been and will continue to be generated by Pfizer and its collaboration partner, BioNTech, without the use of Government funding.

As between Pfizer and the Government, Pfizer shall own any and all data generated by Pfizer and/or BioNTech (i) as of the Effective Date of this Statement of Work, or (ii) after the Effective Date of this Statement of Work, outside the scope of this Statement of Work (“Background Data”). As between Pfizer and the Government, Pfizer also shall own any and all data generated by Pfizer

within the scope of this Statement of Work (“Subject Data”). For the avoidance of doubt, the parties do not anticipate Pfizer generating any Subject Data using Government funding.

Pfizer hereby grants the Government a non-exclusive license to use any Background Data and Subject Data contained in the deliverables pursuant to Section 4, but solely to the extent necessary for the Government to perform its obligations under this Agreement and arrange administration of the doses delivered in accordance with FDA and other applicable regulations.

The Government will provide Pfizer with no less than thirty (30) days’ written notice prior to releasing, in response to a Freedom of Information Act (FOIA) request, any document submitted by Pfizer to Government. During this 30-day period, Pfizer shall have the right to notify Government which documents, if any, contain trade secrets of Pfizer, BioNTech or their respective collaboration partners (or other information legally withholdable from release under FOIA).

7.3 Regulatory Rights

Pfizer will seek and anticipates that it will achieve FDA-approval or authorization and commercialization of Pfizer and BioNTech’s mRNA-based Vaccine against SARS-CoV-2 Coronavirus (the “Technology”).

Pfizer and the Government agree to the following:

Communications. Pfizer will provide the Government with all formal written responses from the FDA regarding the Technology (b) (4).

Pfizer also shall use diligent efforts to provide to the USG Government any and all FDA inspection and compliance notices, observations, and responses from Pfizer (b) (4). The Government shall limit distribution of these documents to HHS and DoD regulatory personnel, and may share the substance of the documents to others within the DoD and HHS that have a need to know.

DoD Medical Product Priority. PL 115-92 allows the DoD to request, and FDA to provide, assistance to expedite development of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. Pfizer recognizes that only the DoD can utilize PL 115-92. (b) (4)

Pfizer shall submit Public Law 115-92 Sponsor Authorization Letter that will be delivered to the designated OWS POC(s) (b) (4).

8.0 SECURITY / EXPORT CONTROL

As set forth more fully in Section 11.7, the provisions of this Section 8 supersede the provisions of Article XII (Export Controls). The following requirements of Article XVII (Security and

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OPSEC) of the Base Agreement are not applicable and are therefore self-deleting and replaced by this Section: all references to CUI and CDI, sub-paragraphs (1) through (20) excepting sub-Paragraphs (3)(e), (4), and (20)(d).

The security classification for this effort is Unclassified. As it is currently not anticipated that any Controlled Unclassified Information (“CUI”) will be obtained under this Statement of Work, other than Pfizer proprietary information, DFARS 252.204-8012 shall not apply. In addition, the training requirements of Article XVII of the Base Agreement shall not apply. However, if CUI is provided, Pfizer will keep all such information confidential and will only give access to such information to persons with a legitimate need for such access.

Pfizer agrees to comply with all applicable laws regarding commodities and technology subject to this Statement of Work. Pfizer will submit plans and reports as set forth in Section 4.0 above addressing the security topics generally contemplated by Appendix 1 to this Statement of Work. The Government acknowledges that these plans will reflect Pfizer’s established security procedures in place with respect to its facilities and information security, which are at least as protective as would be customary for a global company. Pfizer will use commercially reasonable efforts to implement any further procedures/precautions reasonably requested by the Government with respect to Statement of Work and Appendix 1, at Pfizer’s sole discretion and as long as such implementation would not adversely impact Pfizer’s ordinary operation of its facilities and systems in connection with its other business and products.

9.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)

Intentionally Left Blank.

10.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

As set forth more fully in Section 11.7, the provisions of this Section 10.0 supersede and replace, in their entirety, the provisions of Article XIII (Title and Disposition of Property) of the Base Agreement.

There will be no Government furnished equipment, and no equipment will be funded by the Government under this Statement of Work.

11.0 OTHER

11.1 PREP Act.

In accordance with the Public Readiness and Emergency Preparedness Act (“PREP Act”), Pub. L. No. 109-148, Division C, Section 2, as amended (codified at 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e), as well as the Secretary of HHS’s Declaration Under the Public Readiness and

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Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020, effective Feb. 4, 2020), and amended on April 15, 2020, 85 Fed. Reg. 21012, and on June 8, 2020, 85 Fed. Reg. 34740 (together, the “Prep Act Declaration”):


- (i) This Agreement is being entered into for purposes of facilitating the manufacture, testing, development, distribution, administration, and use of “Covered Countermeasures” for responding to the COVID-19 public health emergency, in accordance with Section VI of the PREP Act Declaration;
- (ii) Pfizer’s performance of this Agreement falls within the scope of the “Recommended Activities” for responding to the COVID-19 public health emergency in accordance with Section III of the PREP Act Declaration; and
- (iii) Pfizer is a “Covered Person” per Section V of the PREP Act Declaration.

Therefore, in accordance with Sections IV and VII of the PREP Act Declaration as well as the PREP Act (42 U.S.C. § 247d-6d), the Department of Defense contracting via assisted acquisition on behalf of the HHS, expressly acknowledges and agrees that the HHS Declaration cited above, specifically its language providing immunity from suit and liability is applicable to this Agreement, as long as Pfizer’s activities fall within the terms and conditions of the PREP Act and the PREP Act Declaration.

The Government may not use, or authorize the use of, any products or materials provided under this Agreement, unless such use occurs in the United States and is protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act declaration of equal or greater scope.

11.2 Terminations. As set forth more fully in Section 11.7, the provisions of this Section 11.2 hereby supersede and replace, in their entirety, Sections 2.03 and 2.06 of the Base Agreement:

(a) (b) (4)



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(b) Stop-Work Orders. Except as required by applicable law or regulation, or judicial or administrative order, the Government shall not have the authority to issue a Stop-Work Order to halt the work contemplated under this Statement of Work.

(c) Consequences of Termination. In the event of termination of this Agreement pursuant to this Section 11.2, or expiration of this Agreement at the end of the period of performance as set forth in Section 3.1, this Agreement shall forthwith become null and void and have no effect, without any liability on the part of any Party; *provided, however*, that Sections 7, 11 and 12 hereof, and Article VIII (Confidential Information) of the Base Agreement, shall survive any termination or expiration of this Agreement; and *provided, further*, that the termination or expiration of this Agreement shall not release any Party hereto of any liability, including any outstanding payments of the Government for doses previously delivered hereunder, which at the time of termination or expiration had already accrued to the other party in respect to any act or omission prior thereto.

11.3 Audits. As set forth more fully in Section 11.7, the provisions of this Section 11.3 hereby supersede and replace, in their entirety, the provisions of Section 5.07 (Financial Records and Reports) of the Base Agreement.

Pfizer's relevant financial records shall not be subject to audit until the Government has provided funds to Pfizer. These records will be subject to audit for a period not to exceed three (3) years after final payment under this Agreement. Pfizer shall have the right to request use of a third-party audit firm to audit Pfizer's books and records maintained in connection with this Agreement; however, in accordance with 10 U.S.C. § 2371b(c) for a period not to exceed three (3) years after final payment under this Agreement, the Comptroller General shall have access to examine the records of any party to the agreement or any entity that participates in the performance of the agreement.

11.4 Disputes. As set forth more fully in Section 11.7, Section 7.02 of the Base Agreement is hereby amended to add the following at the end of said section:

The Government's breach of this Statement of Work may result in money damages and nothing in the Project Agreement (if any) or Base Agreement prevents Pfizer from seeking relief in the United States Court of Federal Claims pursuant to 28 U.S.C. § 1491.

11.5 Timing Estimates. All timing estimates set forth in this Statement of Work are subject to change based on emerging data, regulatory guidance, and manufacturing and technical developments, among other risks.

11.6 Limitation of Liability. The Government acknowledges and agrees that Pfizer's efforts to develop and manufacture a vaccine intended to prevent COVID-19 disease caused by SARS-CoV-2 are aspirational in nature and subject to significant risks and uncertainties. Accordingly, notwithstanding anything to the contrary in this Statement of Work or the Base Agreement, Pfizer shall have no liability for any failure to develop, obtain or maintain U.S. regulatory approval or authorization of such a vaccine in accordance with the estimated schedule described in this Statement of Work.

Even if a vaccine is successfully developed and obtains U.S. regulatory approval or authorization, Pfizer shall have no liability for any failure to deliver doses in accordance with the estimated delivery dates set forth in this Statement of Work to the extent any such change in delivery dates is based on emerging data, regulatory guidance, manufacturing and technical developments, or other risks outside Pfizer's control; *provided, however*, Government retains the right to terminate this Agreement or to issue a Stop-Work Order, as specifically contemplated in Sections 11.2(1) and 11.2(b).

(b) (4)

. This Section 11.6 supersedes the Base Agreement's other liability provisions solely to the extent they are inconsistent with this Statement of Work.

11.7 Order of Precedence. Notwithstanding the provisions of Article XXIII (Order of Precedence) of the Base Agreement, the Parties hereby expressly agree that to the extent any provision of the Project Agreement (if any) or this Statement of Work conflicts with any provision of the Base Agreement, the provision of the Project Agreement (if any) or this Statement of Work, as applicable, shall supersede and replace, in the entirety, the conflicting provision of the Base Agreement and control the relationship of the Parties.

Without limiting the generality of the foregoing, this Section 11.7 shall supersede Article XXIII (Order of Precedence) of the Base Agreement and the terms of this Statement of Work shall constitute "specifically negotiated Project Agreement terms" referenced in the last sentence thereof.

This Statement of Work hereby supersedes, without limitation, the following provisions of the Base Agreement: Section 1.05 (Reporting Requirements), Section 2.03 (Termination Provisions), Section 2.06 (Stop-Work), Section 5.07 (Financial Records and Reports), Section 8.05 (Term), Article IX (Publications), Article X (Patent Rights), Article XI (Data Rights), XII (Export Controls), Article XIII (Title and Disposition of Property), Article XVII (Security and OPSEC), and Sections 21.6-21.15 (Regulations) and the integration clause above the signature block to the Base Agreement.

11.8 (b) (4)

11.9 Non-Traditional Defense Contractor. Pfizer has self-certified that Pfizer meets the definition of a “Nontraditional Defense Contractor” as defined in the Base Agreement and therefore is not subject to the cost-sharing requirement referenced in Article VI of the Base Agreement.

11.10 Confidentiality. As set forth more fully in Section 11.7, the provisions of this Section 11.10 hereby supersede and replace, in their entirety, the provisions of Section 8.05 of the Base Agreement.

The obligations of the Receiving Party under this Section shall continue for a period of ten (10) years from the conveyance of Confidential Information. If Pfizer shall need to disclose trade secret information to the Government, Pfizer and the Government will first determine in good faith whether the Government desires to receive any such trade secret information and if the Government so desires to receive such trade secret information, all such information shall be held by the Government in confidence in perpetuity.

11.11 Announcements. Neither Pfizer nor the Government shall make, or permit any person to make, any public announcement concerning the existence, subject matter or terms of this Agreement, the transactions contemplated by it, or the relationship between the Pfizer and the Government hereunder, without the prior written consent of the other, such consent not to be unreasonably withheld or delayed, except as required by law, any governmental or regulatory authority (including, without limitation, any relevant securities exchange), any court or other authority of competent jurisdiction. Notwithstanding the foregoing, Pfizer and (its collaboration partners) shall have the right, but not the obligation, to prepare and submit scientific publications and release information to the public about its Covid-19 development program, without the Government’s consent or involvement. This section supersedes and replaces Article IX of the Base Agreement.

12.0 AGREEMENTS OFFICER’S REPRESENTATIVE (AOR) AND ALTERNATE AOR CONTACT INFORMATION

AOR

NAME: (b) (6)

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MAILING ADDRESS:

EMAIL: (b) (6)

PHONE: (b) (6)

AGENCY NAME/DIVISION/SECTION: BARDA/ASPR/HHS

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Appendix 1: Clause for MCDC Consortium Other Transaction Authority Agreements

Standard Language OWS for Consortium OTA

Required MCDC Base Agreement Modifications

The Medical CBRN Consortium (MCDC) Base Agreement, Article XVII, SECURITY & OPSEC shall apply to this Project Agreement. In addition, the below language shall replace Paragraph 6 of Article XVII of the MCDC Base Agreement.

(6) Access and General Protection/Security Policy and Procedures. This standard language text is applicable to ALL PAH employees working on critical program information or covered defense information related to Operation Warp Speed (OWS), and to those with an area of performance within an Army controlled installation, facility or area. PAH employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The PAH also shall provide all information required for background checks necessary to access critical program information or covered defense information related to OWS, and to meet installation access requirements to be accomplished by installation Provost Marshal Office, Director of Emergency Services or Security Office. The PAH workforce must comply with all personal identity verification requirements as directed by DOD, HQDA and/or local policy. In addition to the changes otherwise authorized by the changes clause of this agreement, should the Force Protection Condition (FPCON) at any individual facility or installation change, the Government may require changes in PAH security matters or processes.

Required SOW Language for Deliverables (in body of SOW or Deliverables Section)

Information Security

Classification guidance for Operation Warp Speed - The security level for this agreement is UNCLASSIFIED.

“Controlled technical information,” “covered contractor information system,” “covered defense information,” “cyber incident,” “information system,” and “technical information” are defined in DFARS Clause 252.204-7012, Safeguarding Covered Defense Information and Cyber Incident Reporting.

Personnel Security

In addition to the industry standards for employment background checks, The Contractor must be willing to have key individuals, in exceptionally sensitive positions, identified for additional vetting by the United States Government.

Supply Chain Resiliency Plan

The contractor shall develop and submit within 30 calendar days after contract award, a comprehensive Supply Chain Resiliency Program that provides identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods.

- a) A critical component is defined as any material that is essential to the product or the manufacturing process associated with that product. Included in the definition are consumables and disposables associated with manufacturing. NOT included in the definition are facility and capital equipment.

Consideration of critical components includes the evaluation and potential impact of raw materials, excipients, active ingredients, substances, pieces, parts, software, firmware, labeling, assembly, testing, analytical and environmental componentry, reagents, or utility materials which are used in the manufacturing of a drug, cell banks, seed stocks, devices and key processing components and equipment. A clear example of a critical component is one where a sole supplier is utilized.

The contractor shall identify key equipment suppliers, their locations, local resources, and the associated control processes at the time of award. This document shall address planning and scheduling for active pharmaceutical ingredients, upstream, downstream, component assembly, finished drug product and delivery events as necessary for the delivery of product.

- a) Communication for these requirements shall be updated as part of an annual review, or as necessary, as part of regular contractual communications.
- b) For upstream and downstream processing, both single-use and re-usable in-place processing equipment, and manufacturing disposables also shall be addressed. For finished goods, the inspection, labeling, packaging, and associated machinery shall be addressed taking into account capacity capabilities.
- c) The focus on the aspects of resiliency shall be on critical components and aspects of complying with the contractual delivery schedule. Delivery methods shall be addressed, inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the contractually agreed deliveries.

The contractor shall articulate in the plan, the methodology for inventory control, production planning, scheduling processes and ordering mechanisms, as part of those agreed deliveries.

- a) Production rates and lead times shall be understood and communicated to the Contracting/Agreement Officer or the Contracting/Agreement Officer's Representative as necessary.
- b) Production throughput critical constraints should be well understood by activity and by design, and communicated to contractual personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.

Reports for critical items should include the following information:

- a) Critical Material
- b) Vendor
- c) Supplier, Manufacturing / Distribution Location
- d) Supplier Lead Time
- e) Shelf Life
- f) Transportation / Shipping restrictions

The CO and COR reserve the right to request un-redacted copies of technical documents, during the period of performance, for distribution within the Government. Documents shall be provided within ten (10) days after CO issues the request. The Contractor may arrange for additional time if deemed necessary, and agreed to by the CO.

Manufacturing Data Requirements:

The Contractor shall submit within 30 calendar days after award detailed data regarding project materials, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing, processing, and fill/finish sites; and location and nature of non-clinical and clinical studies sites. The Government may provide a table in tabular format for Contractor to be used to submit such data which would include but not be limited to the following:

- Storage/inventory of ancillary materials (vials, needles, syringes, etc.)
- Shipment of ancillary materials (vials, needles, syringes, etc.)
- Disposal of ancillary materials (vials, needles, syringes, etc.)
- Seed development or other starting material manufacturing
- Bulk drug substance and/or adjuvant production
- Fill, finish, and release of product or adjuvant
- Storage/inventory of starting materials, bulk substance, or filled/final product or adjuvant
- Stability information of bulk substance and/or finished product
- Shipment of bulk substance of final product
- Disposal of bulk substance or final product

Product Development Source Material and Manufacturing Reports and Projections:

The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and location and nature of non-clinical and clinical study sites.

The Contractor will provide manufacturing reports and manufacturing dose tracking projections/actuals utilizing the “COVID-19 Dose Tracking Templates”, on any contract/agreement that is manufacturing product

- Contractor will submit Product Development Source Material Report
 - Within month of contract award
 - Within 30 days of substantive changes are made to sources and/or materials
 - Or on the 6th month contract anniversary.
- Contractor will update the Dose Tracking Template weekly, during manufacturing campaigns and COVID response, with the first deliverable submission within 15 days of award/modification
- The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission
- If corrective action is recommended, Contractor must address all concerns raised by the Government in writing

Contractor Locations:

The contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors.

Contractor will submit Work Locations Report:

- Within 5 business days of contract award
- Within 30 business days after a substantive location or capabilities change
- Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO

Required SOW Language for Security Section

This project requires an OPSEC Plan and a Security Plan.

The contractor shall develop a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the Government requirement. This plan shall establish security practices and procedures that demonstrate how the contractor will meet and adhere to the security requirements outlined below prior to the commencement of product manufacturing, and shall be delivered to the Government within 30 calendar days of award. The contractor shall also ensure all subcontractors, consultants, researchers, etc. performing work on behalf of this effort, comply with all Operation Warp Speed and Project Agreement security requirements and prime contractor security plans.

- a) The Government will review in detail and submit comments within ten (10) business days to the Contracting Officer (CO) to be forwarded to the Contractor. The Contractor shall review the Draft Security Plan comments, and, submit a Final Security Plan to the U.S. Government within thirty (10) calendar days after receipt of the comments.
- b) The Security Plan shall include a timeline for compliance of all the required security measures outlined by the Government.
- c) Upon completion of initiating all security measures, the Contractor shall supply to the Contracting Officer a letter certifying compliance to the elements outlined in the Final Security Plan.

At a minimum, the Final Security Plan shall address the following items:

Security Requirements:

1. Facility Security Plan

Description: As part of the partner facility's overall security program, the contractor shall submit a written security plan with their proposal to the Agreement Officer for review and approval by Operation Warp Speed security subject matter experts. The performance of work under the Project Agreement will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:

Security Administration	<ul style="list-style-type: none">• organization chart and responsibilities• written security risk assessment for site• threat levels with identification matrix (High, Medium, or Low)• enhanced security procedures during elevated threats• liaison procedures with law enforcement• annual employee security education and training program
Personnel Security	<ul style="list-style-type: none">• policies and procedures• candidate recruitment process• background investigations process• employment suitability policy• employee access determination• rules of behavior/ conduct• termination procedures• non-disclosure agreements
Physical Security Policies and Procedures	<ul style="list-style-type: none">• internal/external access control• protective services• identification/badging• employee and visitor access controls• parking areas and access control• perimeter fencing/barriers• product shipping, receiving and transport security procedures• facility security lighting• restricted areas• signage• intrusion detection systems• alarm monitoring/response• closed circuit television• product storage security• other control measures as identified
Information Security	<ul style="list-style-type: none">• identification and marking of sensitive information• access control• storage of information• document control procedures• retention/ destruction requirements
Information Technology/Cyber Security Policies and Procedures	<ul style="list-style-type: none">• intrusion detection and prevention systems• threat identification• employee training (initial and annual)• encryption systems• identification of sensitive information/media• password policy (max days 90)• lock screen time out policy (minimum time 20 minutes)• removable media policy• laptop policy• removal of IT assets for domestic/foreign travel• access control and determination• VPN procedures• WiFi and Bluetooth disabled when not in use

	<ul style="list-style-type: none"> • system document control • system backup • system disaster recovery • incident response • system audit procedures • property accountability
<p>2. Site Security Master Plan</p> <p>Description: The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; IT Server Room; Product Storage Freezer/Room; and bio-containment laboratories.</p>	
<p>3. Site Threat / Vulnerability / Risk Assessment</p> <p>Description: The partner facility shall provide a written risk assessment for the facility addressing: criminal threat, including crime data; foreign/domestic terrorist threat; industrial espionage; insider threats; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies. The assessment should be updated annually.</p>	
<p>4. Physical Security</p> <p>Description:</p>	
Closed Circuit Television (CCTV) Monitoring	<ul style="list-style-type: none"> a) Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored. b) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. c) Video recordings must be maintained for a minimum of 30 days. d) CCTV surveillance system must be on emergency power backup. e) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. f) Video recordings must be maintained for a minimum of 30 days. g) CCTV surveillance system must be on emergency power backup.
Facility Lighting	<ul style="list-style-type: none"> a) Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings. b) Lighting must have emergency power backup. c) Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.
Shipping and Receiving	<ul style="list-style-type: none"> a) Must have CCTV coverage and an electronic access control system. b) Must have procedures in place to control access and movement of drivers picking up or delivering shipments. c) Must identify drivers picking up Government products by government issued photo identification.
Access Control	<ul style="list-style-type: none"> a) Must have an electronic intrusion detection system with centralized monitoring. b) Responses to alarms must be immediate and documented in writing. c) Employ an electronic system (i.e., card key) to control access to areas where assets critical to the contract are located (facilities, laboratories, clean rooms, production facilities, warehouses, server rooms, records storage, etc.). d) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas. e) Must have a system that provides a historical log of all key access transactions and kept on record for a minimum of 12 months.

	<ul style="list-style-type: none"> f) Must have procedures in place to track issuance of access cards to employees and the ability to deactivate cards when they are lost or an employee leaves the company. g) Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of 12 months. h) Should have written procedures to prevent employee piggybacking access i) to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access. j) Must have a written manual key accountability and inventory process. k) Physical access controls should present a layered approach to critical assets within the facility.
Employee/Visitor Identification	<ul style="list-style-type: none"> a) Should issue company photo identification to all employees. b) Photo identification should be displayed above the waist anytime the employee is on company property. c) Visitors should be sponsored by an employee and must present government issued photo identification to enter the property. d) Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises at all times.
Security Fencing	Requirements for security fencing will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces	Requirements for security officers will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces Operations	<ul style="list-style-type: none"> a) Must have in-service training program. b) Must have Use of Force Continuum. c) Must have communication systems available (i.e., landline on post, cell phones, handheld radio, and desktop computer). d) Must have Standing Post Orders. e) Must wear distinct uniform identifying them as security officers.
5. Security Operations	
Description:	
Information Sharing	<ul style="list-style-type: none"> a) Establish formal liaison with law enforcement. b) Meet in person at a minimum annually. Document meeting notes and keep them on file for a, minimum of 12 months. POC information for LE Officer that attended the meeting must be documented. c) Implement procedures for receiving and disseminating threat information.
Training	<ul style="list-style-type: none"> a) Conduct new employee security awareness training. b) Conduct and maintain records of annual security awareness training.
Security Management	<ul style="list-style-type: none"> a) Designate a knowledgeable security professional to manage the security of the facility. b) Ensure subcontractor compliance with all Government security requirements.
6. Personnel Security	
Description:	
Records Checks	Verification of social security number, date of birth, citizenship, education credentials, five-year previous employment history, five-year previous residence history, FDA disbarment, sex offender registry, credit check based upon position within the company; motor vehicle records check as appropriate; and local/national criminal history search.
Hiring and Retention Standards	<ul style="list-style-type: none"> a) Detailed policies and procedures concerning hiring and retention of employees, employee conduct, and off boarding procedures.

	b) Off Boarding procedures should be accomplished within 24 hour of employee leaving the company. This includes termination of all network access.
7. Information Security	
Description:	
Physical Document Control	<ul style="list-style-type: none"> a) Applicable documents shall be identified and marked as procurement sensitive, proprietary, or with appropriate government markings. b) Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet/desk or other storage device and not be left unattended. c) Access to sensitive information should be restricted to those with a need to know.
Document Destruction	Documents must be destroyed using approved destruction measures (i.e, shredders/approved third party vendors / pulverizing / incinerating).
8. Information Technology & Cybersecurity	
Description:	
Identity Management	<ul style="list-style-type: none"> a) Physical devices and systems within the organization are inventoried and accounted for annually. b) Organizational cybersecurity policy is established and communicated. c) Asset vulnerabilities are identified and documented. d) Cyber threat intelligence is received from information sharing forums and sources. e) Threats, vulnerabilities, likelihoods, and impacts are used to determine risk. f) Identities and credentials are issued, managed, verified, revoked, and audited for authorized devices, users and processes. g) Users, devices, and other assets are authenticated (e.g., single-factor, multifactor) commensurate with the risk of the transaction (e.g., individuals' security and privacy risks and other organizational risks)
Access Control	<ul style="list-style-type: none"> a) Limit information system access to authorized users. b) Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access. c) Limit physical access to information systems, equipment, and server rooms with electronic access controls. d) Limit access to/ verify access to use of external information systems.
Training	a) Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.
Audit and Accountability	<ul style="list-style-type: none"> a) Create, protect, and retain information system audit records to the extent needed to enable the monitoring, analysis, investigation, and reporting of unlawful, unauthorized, or inappropriate system activity. Records must be kept for minimum must be kept for 12 months. b) Ensure the actions of individual information system users can be uniquely traced to those users. c) Update malicious code mechanisms when new releases are available. d) Perform periodic scans of the information system and real time scans of files from external sources as files are downloaded, opened, or executed.
Configuration Management	<ul style="list-style-type: none"> a) Establish and enforce security configuration settings. b) Implement sub networks for publically accessible system components that are physically or logically separated from internal networks.

Contingency Planning	a) Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times.
Incident Response	a) Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery of cybersecurity incidents. Exercise this capability annually.
Media and Information Protection	a) Protect information system media, both paper and digital. b) Limit access to information on information systems media to authorized users. c) Sanitize and destroy media no longer in use. d) Control the use of removable media through technology or policy.
Physical and Environmental Protection	a) Limit access to information systems, equipment, and the respective operating environments to authorized individuals. b) Intrusion detection and prevention system employed on IT networks. c) Protect the physical and support infrastructure for all information systems. d) Protect information systems against environmental hazards. e) Escort visitors and monitor visitor activity.
Network Protection	Employ intrusion prevention and detection technology with immediate analysis capabilities.
9. Transportation Security	
Description: Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage.	
Drivers	a) Drivers must be vetted in accordance with the Government Personnel Security Requirements. b) Drivers must be trained on specific security and emergency procedures. c) Drivers must be equipped with backup communications. d) Driver identity must be 100 percent confirmed before the pick-up of any Government product. e) Drivers must never leave Government products unattended, and two drivers may be required for longer transport routes or critical products during times of emergency. f) Truck pickup and deliveries must be logged and kept on record for a minimum of 12 months.
Transport Routes	a) Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency. b) Transport routes should be continuously evaluated based upon new threats, significant planned events, weather, and other situations that may delay or disrupt transport.
Product Security	a) Government products must be secured with tamper resistant seals during transport, and the transport trailer must be locked and sealed. <ul style="list-style-type: none"> • Tamper resistant seals must be verified as “secure” after the product is placed in the transport vehicle. b) Government products should be continually monitored by GPS technology while in transport, and any deviations from planned routes should be investigated and documented. c) Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.
10. Security Reporting Requirements	
Description: The partner facility shall notify the Agreement Officer within 24 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of government products. The facts and circumstances associated with these incidents will be documented in writing for government review.	
11. Security Audits	

Description: The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and subcontractor.