

From: Schofield, Robin (NIH/NIAID) [E] <robin.schofield@nih.gov>
Sent: Wednesday, January 27, 2021 3:32 PM EST
To: FOIA <foia@americanoversight.org>
CC: Moore, Marg (NIH/NIAID) [E] <mmoore@niaid.nih.gov>
Subject: Response to FOIA Requests 55254, 55255 and 55256

EXTERNAL SENDER

Dear Mr. Evans,

On October 15, 2020 you submitted three requests under the Freedom of Information Act (FOIA) to multiple addressees including the National Institute of Allergy and Infectious Diseases (NIAID) requesting that we search the records of the "Office of the Director of the Dale and Betty Bumpers Vaccine Research Center within the National Institute of Allergy and Infectious Diseases" for the following records relating to contracts issued under the Department of Health and Human Services (HHS) initiative Operation Warp Speed:

55254: Complete copies (including attachments) of the contract(s), amendment(s), MOU(s), or other written agreement(s) between (a) Advanced Technology International, Inc (ATI) and (b) the entities listed below regarding the development of coronavirus vaccines or therapeutics: Novavax, Inc.; Pfizer; BioNTech; Sanofi Pasteur (and its subsidiary Protein Sciences); GlaxoSmithKline; and Johnson and Johnson.

55255: All records reflecting the terms/conditions of contracts, amendments, MOUs and written agreements between (a) Advanced Technology International and (b) the entities listed below regarding the development of coronavirus vaccines or therapeutics: Novavax, Inc; Pfizer; BioNtech; Sanofi Pasteur; GlaxoSmithKline; and Johnson & Johnson.

55256: Any interim assessments, reports, or projections provided by or on behalf of Advanced Technology International, Inc., or any ATI subcontractors or grantees listed below, regarding the development and future distribution and administration of any COVID-19 vaccines or therapeutics : Novavax, Psizer; BioNTech; Sanofi Pastuer; GlaxoSmithKline; and Johnson & Johnson.

It has come to our attention that HHS as the custodian of these records has proactively posted them in a reading room on the HHS's FOIA Website:

<https://www.hhs.gov/foia/electronic-reading-room/index.html>

Specific links below:

<https://www.hhs.gov/sites/default/files/novavax-covid-19-vaccine-contract.pdf>

<https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf>

<https://www.hhs.gov/sites/default/files/sanofi-covid-19-vaccine-contract.pdf>

<https://www.hhs.gov/sites/default/files/gsk-exhibit-a-contract-data-requirements-list.pdf>

<https://www.hhs.gov/sites/default/files/glaxosmithkline-covid-19-vaccine-contract.pdf>

<https://www.hhs.gov/sites/default/files/janssen-corp-covid-19-vaccine-contract.pdf>

For any additional information not provided on HHS's FOIA Website, Army Contracting Command - New Jersey would likely have responsive documents.

Due to the fact that these documents are already in the public domain or are the records of other Federal agencies, NIAID is administratively closing these three requests.

Regards,

Robin L. Schofield, MPS
FOIA Coordinator
National Institute of Allergy and Infectious Diseases



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

REPLY TO
ATTENTION OF

06 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 Undefined “Rapid (WF10) Advanced Research & Development to Large Scale Manufacturing of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus” (Novavax, Inc.)

REF: Novavax Request for Technical Direction Letter, RPP 20-11 under OTA W15QKN-16-9-1002 for Objective PRE-20-11, dated 06 July 2020

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

Dear Ms. (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 Novavax as the awardee. The Government requests that a Cost-Plus-Fixed-Fee Project Agreement be issued to Novavax 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).

The Government received the undefinitized Rough Order of Magnitude (ROM) proposal update on 02 July 2020, and reviewed the costs and documentation accordingly. Based upon the acceptable update of Novavax’s proposal for “Rapid (WF10) Advanced Research & Development to Large Scale Manufacturing of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus” 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 ROM that has been analyzed and concurred to by the Government, you are hereby directed to issue a Undefinitized Project Agreement to Novavax for the subject project. The total project value will be determined fair and reasonable via a subsequent modification to the project agreement.

The total approved cost to the Government for this effort is not to exceed \$1,600,629,522.00. The break-out of the costs is as follows: \$1,600,434,522.00 to perform project efforts included in the SOW and \$195,000.00 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 \$1,600,534,523.00 of available funding, comprised of \$1,600,339,523.00 for the Project Agreement and \$195,000.00 for the CMF Special Allocation. While the identified amounts are incorporated into the OTA, they are subject to the limitations in the undefinitized addendum. Specifically, member funding is limited to 50% of the member ceiling. The COVID-19 work shall be tracked separately using the funding obligated via modification P00074. In alignment with the special allocation conditions, it is noted that this project has a base period of performance of eighteen (18) months, with a projected completion date of 31 December 2021. A customized clause for the special allocation, will be incorporated into the funding modification for this prototype project.

This Project Agreement is anticipated to be incrementally funded. The Government reserves the right to award future milestones/fund additional months of project tasks. If the Government decides to do so, the MCDC member will be notified via ATI. The Government's liability will never exceed the current amount of funding obligated under the Project Agreement. The Project Agreement Holder shall notify ATI when they are approaching (b) (6) of current funding obligated in incurred costs by written notice.

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.

As this project agreement is undefinitized, please see Attachment 2 of this letter for conditions to be included in the project agreement.

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,

(b) (6)

(b) (6)

Agreements Officer

Signed by: (b) (6)

Attachments:

Attachment 1: MCDC2011-001 - Novavax - 7-6-2020

Attachment 2: UPA Addendum - MCDC RPP 20-11 - Novavax

Attachment 3: OPSEC Language Addendum

**Statement of Work
For
Rapid (WF10) Advanced Research & Development to Large Scale Manufacturing of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus**

RPP #: 20-11

Project Identifier: MCD2011-001

Consortium Member: Novavax, Inc.

Title of Proposal: Rapid (WF10) Advanced Research & Development to Large Scale Manufacturing of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus

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

To meet the needs of the Coronavirus Disease 2019 (COVID-19) pandemic, the United States Government (USG) is identifying and will support development and at-scale manufacturing of selected vaccine candidates, to ensure timely availability to the US population when needed. This is the primary focus of the mission being executed by the Department of Health and Human Services (HHS) and Department of Defense (DoD), in support of Operation Warp Speed (OWS).

The USG is interested in pursuing prototype vaccines that are in an advanced stage of development, and will support companies that can, in parallel with nonclinical, clinical and regulatory development, rapidly establish the manufacturing capacity required to meet the USG's objective of supplying a safe and effective Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) vaccine to the entire US population. The USG is tasked with marshaling the efforts of the US biotechnology industry to achieve this goal.

1.2 Definition of the Prototype Project

Consistent with USG objectives, the "prototype project" under this agreement is defined as the manufacture and delivery of 100M doses of a SARS-CoV-2 vaccine, NVX-CoV2373, which is suitable for use in humans under a sufficiently informed deployment strategy, and the advanced positioning of a stockpile of critical long lead raw materials for the Matrix-M adjuvant. As such, the "prototype project" will effectively demonstrate Novavax's ability to rapidly stand up large scale manufacturing and seamlessly transition into ongoing production.

The NVX-CoV-2373 vaccine is comprised of the Matrix-M™ adjuvant, and antigen (SARS-CoV-2 spike protein). The vaccine is filled into a multi-dose vial (b) (4) and is stored at refrigerated temperature (2-8°C).

Successful development of the prototype will demonstrate Novavax's ability to rapidly stand up large scale manufacturing and seamlessly transition into ongoing production capability, in order to rapidly manufacture to meet surge requirements with little advance notification, and

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1

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demonstrate capability to stockpile and distribute large quantities of the vaccine to respond when needed, including in order to supply use in clinical studies, under an Emergency Use Authorization (EUA), or pursuant to other clearance from the U.S. Food and Drug Administration (FDA).

Successful completion of the prototype will require three coordinated and integrated lines of effort:

- a) Large scale manufacturing, compliant with 21 CFR Parts 210 and 211, and the Drug Supply Chain Security Act (DSCA), to the extent applicable at the time of manufacturing by statute and FDA interpretive guidance thereof.
- b) Parallel nonclinical and clinical studies required to determine if the vaccine is safe and effective.
- c) Compliance with all applicable U.S. regulatory requirements.

It is important to note that while results of nonclinical and clinical studies are critical to develop use case scenarios and, in turn, inform the USG's deployment strategy as it relates to product manufactured under this agreement, successful development of the prototype is dependent only on the validity of data from these studies. The degree to which the data are "positive" or "negative" is not a factor in demonstration of the prototype.

1.3 Follow-on Activity

This prototype project includes unpriced options for follow-on production/procurement. During the performance of the prototype, the USG and Novavax will negotiate the scope and price of production/procurement. If the prototype project is successful, the USG may then enter into follow-on production/procurement by executing these options through a separate stand-alone production/procurement agreement, to be negotiated in terms of scope and price as described in the following paragraph.

In accordance with 10.U.S.C. 2371b(f), and upon demonstration of the prototype, or at the accomplishment of particularly favorable or unexpected results that would justify transitioning to production/procurement, EUA, or Biologics License Application (BLA) approved by the FDA, the USG and Novavax may enter into a non-competitive production/procurement follow-on agreement or contract for additional production/procurement, to partially or completely meet the USG objective of supplying a safe and effective SARS-CoV-2 vaccine to vaccinate up to 300M people in the targeted population ($\approx$ 560M additional doses).

1.4 Scope

Novavax has defined a scope of activities in order to successfully develop the prototype, as defined above. The scope is based on the following assumptions regarding manufacturing and clinical dose:

- Manufacturing Assumptions and Clinical Dose
 - The NVX-CoV-2373 vaccine is comprised of the Matrix-M™ adjuvant, and antigen (SARS-CoV-2 spike protein).

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2

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- A dose range of 5-25 μg of antigen is under clinical study. The anticipated dose based on clinical data obtained to date is μg of antigen with μg of Matrix-M adjuvant.
- For planning purposes, the μg antigen/dose) has been used and the calculations in this scope of work have been based on this dose.
- The antigen production is the rate-limiting step in vaccine production. The Matrix-M adjuvant will be available prior to antigen production. Dose production has been calculated based on the availability of antigen. Novavax is planning on a batch-by-batch rapid fill/finish once antigen is manufactured and available.
- The estimated production schedule based on the μg antigen/dose (base case) and μg antigen /dose (anticipated case) is in the table below:

Dosage	Estimated Schedule of Cumulative Doses Manufactured by Month				
	Oct 2020	Nov 2020	Dec 2020	Jan 2021	Feb 2021
μg /dose (base case)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
μg /dose (anticipated case)	(b) (4)	(b) (4)	100,000,000*		

*Actual cumulative projected production at μg /dose is (b) (4) in December 2020. Some doses may be in progress at the end of December 2020.

**Actual cumulative projected production at μg /dose is (b) (4) in February 2021.

The scope includes the following activities:

o Manufacturing

- Manufacturing of 100M doses (at μg /dose, (b) (4)) of NVX-CoV-2373 vaccine in 2020 for distribution to the Government upon EUA under section 564 of the Food, Drug, and Cosmetic (FD&C) Act or a biologics licensure granted under Section 351(a) of the Public Health Service Act by the U.S. FDA.
- Establishment of large-scale current Good Manufacturing Practice (cGMP) manufacturing capacity compliant with 21 CFR Parts 210 and 211, and the DSCA to the extent applicable at the time of manufacturing by statute and FDA interpretive guidance thereof.
- Comparability among clinical vaccine lots and commercial lots using a comparability protocol linked to the product associated with the Phase 1 clinical study. For adjuvant components, the same raw material lot(s) will be used for the current and new Contract Manufacturing Organization (CMO) processes for the comparability protocol, and the same test lab will be used to ensure only process differences are being evaluated.
- Validation of manufacturing processes will be performed to cGMP standards.

o Clinical

- Phase 3 pivotal clinical trial harmonized with USG clinical strategies.

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- A Phase 3 clinical trial in pediatric populations (<18 years).
- Phase 2 studies in at-risk subpopulations (co-morbidities, (b) (4), immunocompromised), as well as studies to support manufacturing site comparability.
- Non-clinical
 - Studies to support EUA and regulatory approval (BLA).
- Regulatory
 - EUA submission when data supports it, while maintaining progress toward eventual BLA submission.
 - BLA submission when appropriate.
 - Regulatory support activities (Investigational New Drug (IND) submissions) for manufacturing, clinical, non-clinical studies.
 - Meetings as-needed with regulators.
- Project Management
 - Mandatory reporting requirements, as described in the Base Agreement.
 - Submission of Monthly Progress Reports. Format will be agreed on by the contractor and Agreements Officer's Representative (AOR), and will include both technical and financial status and expenditure forecast.
 - Facilitation of biweekly teleconferences with Novavax and USG Subject Matter Experts.
 - Final prototype project report and applicable patents report(s).
 - Work Breakdown Structure (WBS) and Integrated Master Schedule (IMS).
 - All Regulatory correspondence relevant to the scope of work proposed, including communications with the FDA, and all submissions.

1.4.1 Novavax Project Plan

This is Novavax's plan as of the date of the submission. Novavax desires to move quickly to large scale development as rapidly as possible, in order to meet the objectives of this proposal. As the COVID-19 pandemic is an evolving situation, Novavax may need to adapt its plan in response to FDA guidance, opportunities for manufacturing efficiencies, and clinical trial data.

1.5 Resolution of Conflicting Language

If there is a conflict between the Project Agreement (of which this Statement of Work is part) and the Base Agreement (Medical CBRN Consortium (MCDC) Base Agreement No.: 2020-530), the Project Agreement language will supersede and control the relationship of the parties.

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4

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2.0 APPLICABLE REFERENCES

N/A

3.0 REQUIREMENTS

3.1 Major Task: cGMP Manufacturing of NVX-CoV-2373 compliant with 21 CFR 210 and 211

3.1.1 Subtask: Raw Materials – Obtain Critical Starting Materials for Adjuvant Manufacturing

Sufficient Saponin to manufacture up to 100M vaccine doses will be purchased (Desert King, headquartered in San Diego, CA, facilities in Chile). Long-lead, critical, and limited-supply materials (b) (4)

(b) (4) will be purchased for the additional 560M vaccine doses to meet the contact requirement, in order to ensure capability to rapidly manufacture to meet surge requirements with little advance notification and demonstrate capability to stockpile and distribute large quantities of the vaccine to respond when needed.

3.1.2 Subtask: Raw Materials – Obtain Critical Starting Materials for Antigen and Fill/Finish Manufacturing

Sufficient materials (vials, stoppers, other consumables) to manufacture up to 100M vaccine doses will be purchased (sources TBD).

3.1.3 Subtask: Raw Materials – (b) (4) Intermediates to Produce Matrix-M Adjuvant Matrix-M Adjuvant

(b) (4) to supply large-scale manufacturing of vaccine doses will be manufactured at (b) (4) and PolyPeptide (Torrance, CA & Malmö, Sweden). Technology transfer and start-up of the PolyPeptide facility in Torrance, CA will be completed. Long lead, critical, and limited supply materials will be purchased in order to achieve the goal of large-scale production.

3.1.4 Subtask: Matrix-M Adjuvant Manufacturing to Supply 100M Vaccine Doses

Matrix-M Adjuvant bulk components will be manufactured at ACG Biologics (Seattle, WA) to supply 100M vaccine doses. Technology transfer and start-up of the AGC Bio facility in Seattle will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.5 Subtask: Antigen Manufacturing to Supply 100M Vaccine Doses

Antigen will be manufactured at Fuji (2 sites – College Station, TX and Research Triangle Park, NC) to supply 100M vaccine doses. Technology transfer and scale-up activities will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.6 Subtask: Fill/Finish of 100M Vaccine Doses

100M doses of finished vaccine in (b) (4) vials will be manufactured at Baxter (Bloomington, IN, USA). This will include secondary packaging. Technology transfer and scale-up activities will

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5

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be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.7 Subtask: Shipping and Storage

Novavax assumes that it will maintain a Vendor Managed Inventory (VMI) system for a period of 12 months, with shipments to 10 geographic zones in the USA. Novavax will perform activities to establish compliance with DSCA to the extent applicable at the time of manufacturing, by statute and FDA interpretive guidance thereof.

3.2 Major Task: Clinical Studies

Novavax will perform these clinical trials and deliver the results in an interim Clinical Study Report (CSR) at the completion of enrollment, and the final CSR when available. These trials will be conducted using a Clinical Research Organization (CRO) that is to be determined.

3.2.1 Subtask: Phase 3 Global Efficacy Study, Adults ≥ 18 and < 75 years

Study: Phase 3 – Global Efficacy Study (to be harmonized with other USG studies), 2019nCoV-301.

Population: Adults ≥ 18 years, inclusive of subjects with more severe co-morbid conditions.

Locations: North America, Europe; may include Africa, Asia, Oceania, South America.

Primary Objectives: Clinical efficacy, safety, immunogenicity.

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix (b) (4) – dose determined by Phase 2 dose confirmation study, Placebo; (b) (4)

Enrollment: TOTAL N: ~30,000 (adjusted for expected endpoint incidence). (b) (4)

3.2.2 Subtask: Phase 2 Efficacy Expansion (US), Adults ≥ 18 and < 75 years

Study: Phase 2 - Part 3 efficacy expansion (US), 2019nCoV-204.

Population: Adults ≥ 18 and < 75 years.

Locations: USA.

Primary Objectives: Clinical efficacy, safety, immunogenicity.

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + (b) (4); not greater than (b) (4) to allow for rapid initiation. Placebo. ~0.5 mL dose IM injection, up to 2 doses at Day 0 and Day 21.

Enrollment: TOTAL: N (b) (4). Adjusted for expected event occurrence. Event driven analysis. Initiation of study gated on completion of Phase 1 study, dose-selection and regulatory approval.

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6

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3.2.3 Subtask: Phase 2 Study in Immunocompromised Persons (HIV-positive adult subjects) (Africa)

Study: Phase 2 study in immunocompromised persons (HIV-positive adult subjects) (Africa).

Population: Adults ≥ 18 and < 65 years.

Locations: Republic of South Africa (RSA)

Primary Objectives: Safety, immunogenicity (serum and cellular).

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M1; Placebo, 0.5 mL dose IM injection, up to 2 doses at Day 0 and Day 21.

Enrollment: Total N = 2,640 – 2,880 (with n=240 - 480 HIV+); 1:1 Vaccine to placebo. Initiation gated on completion of Phase 1 study, dose selection, and regulatory approval.

3.2.4 Subtask: (b) (4)

Study: (b) (4).

Population: (b) (4).

Locations: (b) (4).

Primary Objectives: (b) (4).

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix (b) (4) (b) (4).

Enrollment: (b) (4). Initiation gated on benefit:risk assessment (derived from Task 2.3.1 and/or 2.3.2 and/or other Phase 2 studies) and regulatory approval to conduct studies in this vulnerable population.

3.2.5 Subtask: Phase 2 Manufacturing Site Lot Consistency/Comparability Study (US or other)

Study: Phase 2 manufacturing site lot consistency/comparability study (US or other), 2019nCoV-201.

Population: Adults ≥ 18 to < 50 years.

Locations: USA.

Primary Objectives: Safety, immunogenicity.

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + (b) (4).

Enrollment: ~600 per cohort, each cohort having 1:1 randomization with Emergent (antigen)/Novavax AB (adjuvant) manufacturing site and new manufacturing sites. Study size may be adjusted to allow non-inferiority testing.

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7

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3.2.6 Subtask: Phase 2, Maternal Immunization

Study: Phase 2, maternal immunization, (trial ID TBD).

Population: Adults ≥ 18 to < 40 years.

Locations: Global.

Primary Objectives: Safety, immunogenicity.

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M1; Placebo, 0.5 mL dose IM injection, up to 2 doses at Day 0 and Day 22.

Enrollment: Total = 800 mothers + baby. Initiation gated on benefit:risk assessment (derived from Task 2.3.1 and/or 2.3.2 and/or other Phase 2 studies) and regulatory approval to conduct studies in this vulnerable population.

3.2.7 Subtask: Pharmacovigilance; Establishment of Registration Safety Database

A registration safety database will be established to comply with FDA requirements for product safety and licensure.

3.2.8 Subtask: (b) (4)

Study: (b) (4)

Population: (b) (4)

Location: (b) (4)

Primary Objective: (b) (4)

Design: Randomized, observer-blinded, placebo (or active vaccine) control.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix (b) (4)
(b) (4)

Enrollment: TOTAL: N ~12,500 (based on agreed VE, power, and LBCI). (b) (4)
(b) (4). Adjusted for expected event occurrence if robust demonstration of clinical efficacy is required by the FDA. Event driven analysis for study termination.

3.3 Major Task: Non-Clinical Studies

Novavax will perform these non-clinical studies and deliver the results in a study report at completion.

3.3.1 Mouse Study, Immunogenicity

Study 702-100. Immunogenicity (b) (4) in mice for vaccine efficacy profile to comply with FDA guidelines.

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8

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3.3.2 Rhesus Study, Immunogenicity

Study 702-099. Immunogenicity/challenge ((b) (4)) in rhesus monkeys for vaccine efficacy profile to comply with FDA guidelines.

3.3.3 Hamster Study, Immunogenicity

Study 702-102. Immunogenicity/challenge study in hamster ((b) (4)) for vaccine efficacy profile to comply with FDA guidelines.

3.3.4 Mouse Study, T-Cell Immunogenicity

Study 702-103. T-cell immunogenicity/challenge study in mice ((b) (4)) for vaccine efficacy profile to comply with FDA guidelines.

3.3.5 Hamster Study, T-Cell Immunogenicity

Study 702-105. Immunogenicity/challenge study in hamster ((b) (4)) for vaccine efficacy profile to comply with FDA guidelines.

3.3.6 Mouse Study, T-Cell Immunogenicity

Study 702-104. Immunogenicity/challenge study in hamster ((b) (4)) for vaccine efficacy profile to comply with FDA guidelines.

3.3.7 Non-Clinical Studies: Collaboration with Univ. of Maryland School of Medicine

Three studies to study enhancement/inhibition and neutralization, and virus challenge of vaccinated mice:

1. Validation of Spike nanoparticles in cell inhibition studies: In vitro inhibition studies on cell line permissive to r2019-nCoV, readout TBD.
2. Neutralization studies with virus against bleeds from mice, In vitro microneutralization studies on cell line permissive to r2019-nCoV, TCID50 or fluorescence readout (TBD).
3. Virus challenge of vaccinated mice (mice vaccinated outside and shipped to UM for challenge), Challenge of vaccinated mice (shipped in for infection from Novavax), Lung pathology, Titer, viral Ribonucleic Acid (RNA) quantitation, pathology scoring and reports.

3.3.8 Structural Study of COVID-19 Spike Protein and its Complex with Host Receptor (cooperation with Baylor College of Medicine)

Study to determine the structures of recombinant COVID-19. Spike protein in nanoparticles used in Novavax's human vaccine and in complex with its host receptor ACE2. Will obtain a high-resolution cryoEM structure of full-length COVID-19 Spike protein and a high-resolution cryoEM structure of full-length COVID-19 Spike protein in complex with human receptor ACE2.

3.3.9 Neutralizing Assay Histopathology for On-going ((b) (4))

Histopathology readings for current neutralization studies in ((b) (4)). This will support the safety profile of the vaccine for FDA approval.

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9

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3.3.10 Mouse Study, Immunogenicity (b) (4) Studies

Individual immunogenicity studies (b) (4) in mice for vaccine efficacy profile in different sub-populations to comply with FDA guidelines.

3.4 Major Task: Regulatory Affairs

Novavax will conduct the regulatory activities below, including BLA prep and submission, and provide the meeting minutes and applications to the USG.

3.4.1 Subtask: EUA Submission and Supporting Meetings and Regulatory Filings

An EUA will be submitted to the FDA upon obtaining sufficient clinical data. EUA, FDA meetings to support EUA, submission planning support for the Chemistry, Manufacturing, and Controls (CMC) team, EUA strategy and meeting support, and submission preparation support activities, will all be completed.

3.4.2 Subtask: IND Submission Updates and FDA Meetings

This task will include submissions to the IND and possible FDA meetings that will be required prior to the BLA submission.

3.4.3 Subtask: BLA Submission

A BLA will be submitted to the FDA upon obtaining sufficient clinical data, FDA meetings to support BLA, submission planning support for the CMC team, BLA strategy and meeting support, and submission preparation support activities, will all be completed.

3.5 Major Task: Project Management and Reporting

3.5.1 Subtask: Kick-Off Meeting and Initial Baseline Review of IMS

Novavax shall conduct a Kick-Off Meeting and an initial review with the USG of the IMS, upon initiation of the program.

3.5.2 Subtask: Biweekly Meetings with OWS

Novavax shall submit the agenda in advance. Any technical updates shall be provided in advance for the Government team to review. Minutes shall be submitted after the biweekly meeting to the USG.

3.5.3 Subtask: Written Quarterly Reports

Novavax shall submit quarterly reports to the USG.

3.5.4 Subtask: Written Annual Reports

Novavax shall submit the annual reports to the USG.

3.5.5 Subtask: Written Final Report

Novavax shall submit the final report to the USG.

3.6 Optional Task: Follow-On Production

Follow-on production of finished doses of vaccine up to 560M doses.

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10

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MULTI-HHS-NIAID-20-2551, 20-2560, 20-2568-A-000013

4.0 DELIVERABLES

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type/Data Rights
	Manufacturing					
4.1	(b) (4)	(b) (4)	5.1	3.1.1	Reviewer	(b) (4)
4.2	(b) (4)	(b) (4)	5.2	3.1.2	Reviewer	(b) (4)
4.3	(b) (4)	(b) (4)	5.3	3.1.3	Reviewer	(b) (4)
4.4	(b) (4)	(b) (4)	5.4	3.1.4	Reviewer	(b) (4)
4.5	(b) (4)	(b) (4)	5.5	3.1.5	Reviewer	(b) (4)
4.6	(b) (4)	(b) (4)	5.6	3.1.6	Reviewer	(b) (4)
4.7	(b) (4)	(b) (4)	5.7	3.1.7	Reviewer	(b) (4)
	Clinical					

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11

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Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type/Data Rights
4.8	(b) (4)	(b) (4)	5.8	3.2.1	Reviewer	(b) (4)
4.9	(b) (4)	(b) (4)	5.9	3.2.2	Reviewer	(b) (4)
4.10	(b) (4)	(b) (4)	5.10	3.2.3	Reviewer	(b) (4)
4.11	(b) (4)	(b) (4)	5.11	3.2.4	Reviewer	(b) (4)
4.12	(b) (4)	(b) (4)	5.12	3.2.5	Reviewer	(b) (4)
4.13	(b) (4)	(b) (4)	5.13	3.2.6	Reviewer	(b) (4)
4.14	(b) (4)	(b) (4)	5.14	3.2.7	Reviewer	(b) (4)
4.15	(b) (4)	(b) (4)	5.15	3.2.8	Reviewer	(b) (4)
	Non- Clinical					
4.16	(b) (4)	(b) (4)	5.16	3.3.1	Reviewer	(b) (4)
4.17	(b) (4)	(b) (4)	5.17	3.3.2	Reviewer	(b) (4)

¹ As used herein, "Government Purpose Rights" has the meaning set forth in Article XI, Section 11.01(9) of the Base Agreement, as modified by Section 8.2(b) below.

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type/Data Rights
4.18	(b) (4)	(b) (4)	5.18	3.3.3	Reviewer	(b) (4)
4.19	(b) (4)	(b) (4)	5.19	3.3.4	Reviewer	(b) (4)
4.20	(b) (4)	(b) (4)	5.20	3.3.5	Reviewer	(b) (4)
4.21	(b) (4)	(b) (4)	5.21	3.3.6	Reviewer	(b) (4)
4.22	(b) (4)	(b) (4)	5.22	3.3.7	Reviewer	(b) (4)
4.23	(b) (4)	(b) (4)	5.23	3.3.8	Reviewer	(b) (4)
4.24	(b) (4)	(b) (4)	5.24	3.3.9	Reviewer	(b) (4)
4.25	(b) (4)	(b) (4)	5.25	3.3.10	Reviewer	(b) (4)
	Regulatory Affairs					

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13

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Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type/Data Rights
4.26	(b) (4)	(b) (4)	5.26	3.4.1	Reviewer	(b) (4)
4.27	(b) (4)	(b) (4)	5.27	3.4.2	Reviewer	(b) (4)
4.28	(b) (4)	(b) (4)	5.28	3.4.3	Reviewer	(b) (4)
	Project Management					
4.29	(b) (4)	(b) (4)	5.29	3.5.1	Reviewer	(b) (4)
4.30	(b) (4)	(b) (4)	5.30	3.5.2	Reviewer	(b) (4)
4.31	(b) (4)	(b) (4)	5.31	3.5.3	Reviewer	(b) (4)
4.32	(b) (4)	(b) (4)	5.32	3.5.4	Reviewer	(b) (4)
4.33	(b) (4)	(b) (4)	5.33	3.5.4	Reviewer	(b) (4)
4.34	(b) (4)	(b) (4)	5.34	3.5.5	Reviewer	(b) (4)
TBD	(b) (4)	(b) (4)	Option 1	3.6	Reviewer	(b) (4)

5.0 MILESTONE PAYMENT SCHEDULE

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14

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MULTI-HHS-NIAID-20-2551, 20-2560, 20-2568-A-000017

Milestone #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
Manufacturing			
(b) (4)	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Clinical			
(b) (4)	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Non- Clinical			
(b) (4)	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

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15

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MULTI-HHS-NIAID-20-2551, 20-2560, 20-2568-A-000018

Simplified Table: Selected Estimated Costs for Key Deliverables*

Area	Milestone/Deliverable	Start	Finish	Cost
(b) (4)				

* For key deliverables only; does not encompass total project costs.

** Time to obtaining vaccine efficacy data.

6.0 SHIPPING PROVISIONS

The shipment of physical deliverables shall be coordinated with the AOR. Data deliverables shall be provided in accordance with the agreement, and in coordination with the AOR.

7.0 INTELLECTUAL PROPERTY, DATA RIGHTS, AND COPYRIGHTS

7.1 BACKGROUND IP

(a) Ownership. Prior to June 8, 2020, Novavax had funded the development of NVX-CoV2373, and other antecedent vaccine programs relevant to Novavax' proprietary position in the development of NVX-CoV2373, as well as its sf9/baculovirus manufacturing platform, (all "Background IP") through private funding or in collaboration with a funding partner other than the U.S. Government. Such private and non-governmental funding has continued since June 8, 2020 and is expected to continue during the performance of the Project Agreement. A list of all patents and patent applications included in the Background IP is provided below as Enclosure 4. Background IP also consists of (a) manufacturing know-how, including, without limitation, the NVAX-Cov2373 manufacturing process definitions, process development/characterization reports, laboratory scale process procedures, manufacturing records, analytical test methods, product quality target ranges/specifications, quality target product profile, critical quality attributes (collectively "Background Know-How"), (b) data from pre-clinical and clinical research studies, analytical and process development research, and data related to, or generated using, the Background Know-How (collectively, "Background Data"), and (c) proprietary manufacturing materials, including, without limitation, sf9 cell banks (master and working), baculovirus virus stock (master and working), product standards, reference standards, and critical reagents ("Background Materials"). On June 8, 2020, Novavax and the U.S. Department of Defense entered

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17

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into a Letter Contract for specified U.S.-based clinical and manufacturing development of NVX-CoV2373 which acknowledged Background IP and made no explicit U.S. Government claims to Background IP or subsequent data arising therefrom. The U.S. Government hereby acknowledges such Background IP in full and further acknowledges that it has no ownership rights to Novavax Background IP under this Project Agreement.

(b) **Background IP Limited License to Government.** Subject to the terms of the Project Agreement, Novavax grants the U.S. Government a nonexclusive, worldwide, nontransferable, non-sublicenseable license to use the Background IP to the limited extent necessary for the U.S. Government to review and use the Deliverables tendered by Novavax under this Agreement identified in Section 4.0 above, and for no other purpose; provided that the U.S. Government agrees that it may not disclose the Background IP to third parties, or allow third parties to have access to, use, practice or have practiced the Background IP, without Novavax's prior written consent. To the extent that a Deliverable with Foreground IP incorporates or uses Background IP, the Deliverable shall be deemed and considered to comprise Background IP and shall be used by the U.S. Government in accordance with this Background IP Limited License.

(c) **Background IP License to Novavax.** Subject to the terms of the Project Agreement, the U.S. Government grants to Novavax a nonexclusive, worldwide, nontransferable, irrevocable, paid-up license to any intellectual property (including patents and patent applications) to which the U.S. Government has rights thereto, provided that such license is limited to such intellectual property rights necessary to perform Novavax's obligations under the Project Agreement.

7.2 FOREGROUND IP

(a) **Ownership.** Notwithstanding anything in the Base Agreement to the contrary, Novavax owns all rights, title and interest in and to any development, modification, discovery, invention or improvement, whether or not patentable, conceived, made, reduced to practice, or created in connection with activities funded under the Project Agreement, including, without limitation, all data and inventions, and intellectual property rights in any of the foregoing ("Foreground IP").

(b) **Foreground IP Special License.** Subject to the terms of the Project Agreement, Novavax grants the U.S. Government a nonexclusive, worldwide, nontransferable, irrevocable, paid-up license to practice or have practiced the Foreground IP for or on behalf of the U.S. Government ("Foreground IP Special License").

8.0 DATA RIGHTS

Article XI, §11.03 of the Base Agreement is hereby amended, consistent with the "Specifically Negotiated License Rights" capability at Article XI, §§11.01(12) and 11.03(4), as follows:

8.1 Data Ownership.

Novavax owns all rights, title and interest to all Data (as defined in Article XI, Section 11.01(7) of the Base Agreement) generated as a result of the work performed under this Project Agreement, including Subject Data.

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18

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MULTI-HHS-NIAID-20-2551, 20-2560, 20-2568-A-000021

8.2 Rights to Data.

(a) **Subject Data.** Subject to the terms of the Project Agreement, Novavax grants to the U.S. Government a Government purpose rights license to Subject Data that will convert to an unlimited rights license (as the term is defined in Article XI, Section 11.01(14) of the Base Agreement)² after three (3) years from the date of delivery. As used herein, “Subject Data” shall mean Technical Data under Article XI, §11.01(13) of the Base Agreement. Deliverables that are considered Subject Data are identified in the Deliverable Table set forth in Section 4.0 above.

(b) **Transfer of Data.** Each party, upon written request to the other party, shall have the right to review and to request delivery of Subject Data, and delivery of such Data shall be made to the requesting party within two weeks of the request, except to the extent that such Data are subject to a claim of confidentiality or privilege by a third party.

(c) **Background IP Limited License.** To the extent that Subject Data incorporates or uses Background IP, the data shall be deemed and considered to comprise Background IP and shall be used by the U.S. Government in accordance with the Background IP Limited License set forth in Section 7.3 above.

8.3 Background Technical Data Rights Assertions.

Novavax asserts background technical data rights as follows:

The Background Data, as defined in Section 7.1 above, was developed through private funding or in collaboration with a funding partner other than the U.S. Government. Such funding is expected to continue; accordingly, Novavax asserts Background Data as Category A Data pursuant to section 11.02(1) of the Base Agreement and the U.S. Government shall have no rights therein.

9.0 REGULATORY RIGHTS

This agreement includes research with an investigational drug, biologic or medical device that is regulated by the U.S. Food and Drug Administration (FDA) and requires FDA pre-market approval or clearance before commercial marketing may begin. It is expected that this agreement will result in the FDA authorization, clearance and commercialization of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus (the “Technology”). Novavax is the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), emergency use authorization (EUA), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to the FDA) that controls research under this contract. As the Sponsor of the Regulatory Application to the FDA (as the terms “sponsor” and

² As used herein, “Government Use” as used “Purpose Rights” has the meaning set forth in this Section 4.0 means Government purpose rights as defined in the Base Agreement, Article XI, Section 11.01(9).) of the Base Agreement, as modified by Section 8.2(b) below.

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MULTI-HHS-NIAID-20-2551, 20-2560, 20-2568-A-000022

“applicant” are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), Novavax has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application. This clause protects the return on research and development investment made by the U.S. Government in the event of certain regulatory product development failures related to the Technology.

Novavax agrees to the following:

- a. Communications. Novavax will provide the U.S. Government with all communications and summaries thereof, both formal and informal, to or from FDA regarding the Technology and ensure that the U.S. Government representatives are invited to participate in any formal or informal Sponsor meetings with FDA;
- b. Rights of Reference. The U.S. Government is hereby granted a right of reference as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule or analogous applicable law recognized outside of the U.S.) to any Regulatory Application submitted in support of the statement of work for the Project Agreement. When it desires to exercise this right, the U.S. Government agrees to notify Novavax in writing describing the request along with sufficient details for Novavax to generate a letter of cross-reference for the U.S. Government to file with the appropriate FDA office. The U.S. Government agrees that such letters of cross-reference may contain reporting requirements to enable Novavax to comply with its own pharmacovigilance reporting obligations to the FDA and other regulatory agencies. Nothing in this paragraph reduces the U.S. Government’s data rights as articulated in other provisions of the Project Agreement.
- c. DoD Medical Product Priority. PL-115-92 allows the DoD to request, and FDA to provide, assistance to expedite development and the FDA’s review of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. Novavax recognizes that only the DoD can utilize PL 115-92. As such, Novavax will work proactively with the DoD to leverage this law to its maximal potential under this Project Agreement. Novavax shall submit a mutually agreed upon Public Law 115-92 Sponsor Authorization Letter to the U.S. Government within 30 days of award.

10.0 ENSURING SUFFICIENT SUPPLY OF THE PRODUCT

a. In recognition of the Government’s significant funding for the development and manufacturing of the product in this Project Agreement and the Government’s need to provide sufficient quantities of a safe and effective COVID-19 vaccine to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions are met:

- i. Novavax gives written notice, required to be submitted to the Government no later than 15 business days, of:
 - a. any formal management decision to terminate manufacturing of the NVX-CoV-2373 vaccine prior to delivery of 100 million doses to USG;

UNCLASSIFIED

20

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MULTI-HHS-NIAID-20-2551, 20-2560, 20-2568-A-000023

- b. any formal management decision to discontinue sale of the NVX-CoV-2373 vaccine to the Government prior to delivery of 100 million doses to USG; or
- c. any filing that anticipates Federal bankruptcy protection; and
- ii. Novavax has submitted an Emergency Use Authorization under §564 of the FD&C Act or a biologics license application provisions of §351(a) of the Public Health Service Act (PHSA).

b. If both conditions listed in section (a) occur, Novavax, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of the NVX-CoV-2373 vaccine with a third party for exclusive sale to the U.S. Government:

- i. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Background IP as defined in clause 7.1 necessary to manufacture or have manufactured the NVX-CoV2373 vaccine;
- ii. necessary FDA regulatory filings or authorizations owned or controlled by Novavax related to NVX-Cov2373 and any confirmatory instrument pertaining thereto; and
- iii. any outstanding Deliverables contemplated or materials purchased under this Project Agreement.

c. This Article shall be incorporated into any contract for follow-on activities for the Government to acquire and use additional doses of the product. Per section 1.3, the estimated quantity for follow-on production/procurement is approximately 560 million doses.

d. This Article will survive the acquisition or merger of the Contractor by or with a third party. This Article will survive the expiration of this agreement.

11. SECURITY

The security classification level for this effort is UNCLASSIFIED.

12.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)

N/A

13.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

14.0 AGREEMENTS OFFICER'S REPRESENTATIVE (AOR) AND ALTERNATE AOR CONTACT INFORMATION

AOR

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21

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MULTI-HHS-NIAID-20-2551, 20-2560, 20-2568-A-000024

NAME: (b) (6)

EMAIL: (b) (6)

PHONE: (b) (6)

AGENCY NAME/DIVISION/SECTION: Joint Program Executive Office, Joint Program Lead-
Enabling Biotechnologies

Alternate AOR

NAME: TBD

MAILING ADDRESS:

EMAIL:

PHONE:

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

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22

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MULTI-HHS-NIAID-20-2551, 20-2560, 20-2568-A-000025

ENCLOSURE 3: PAYMENT REQUEST INFORMATION

Novavax, Inc. is requesting a payment upon incurring costs, for a total of \$(b) (4) to support the development of NVX-CoV2373 as a vaccine for SARS-CoV-2 Coronavirus. The costs, as outlined below, are incorporated into estimates from subcontractors under milestones associated with manufacture. Novavax will work with subcontractors to ensure the appropriate accounting for pre-award costs during subcontract finalization and subsequent billing.

Projected Expenditures

Cost Element	Task/Purpose	Amount
Materials		
Antigen	(b) (4)	(b) (4)
Adjuvant	(b) (4)	(b) (4)
Adjuvant	(b) (4)	(b) (4)
Reservations Fees		
AGC Bio Seattle	(b) (4)	(b) (4)
PolyPeptide	(b) (4)	(b) (4)
Fuji RTP	(b) (4)	(b) (4)
Fuji Texas	(b) (4)	(b) (4)
Acceleration Fee		
Fuji	(b) (4)	(b) (4)
Subtotal		(b) (4)
Indirect + Fee Burden		(b) (4)
Total Requested Amount		(b) (4)

I. Financial Institution Information
Novavax, Inc.
21 Firstfield Road
Gaithersburg, MD 20878

Name of Bank:

Address:

(b) (4)
(b) (4)
(b) (4)

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ABA #: (b) (4), Checking Account #: (b) (4)
Swift: (b) (4)

II. Justification for Requesting the Payment

- **Materials Costs: - \$(b) (4) Direct Costs**
Procurement and qualification of critical long lead raw materials needed to produce 100M doses of NVX-CoV-2373 in 2020 and to ensure availability of 100M additional doses of NVX-CoV-2373 in 2021. This also includes materials for the purchase of a stockpile of certain critical long lead raw materials for the Matrix-M Adjuvant, necessary to rapidly initiate large-scale manufacturing without a delay. This will ensure timely availability of the vaccine candidate to the US population when needed, a primary mission of HHS in support of OWS.
- **Reservation and Acceleration Fees: - \$(b) (4) Direct Costs**
To quickly address the urgent need presented by the COVID-19 pandemic, Novavax will rely on the reservation of dedicated capacity from manufacturing service providers to be able to produce NVX-CoV-2373. This will ensure timely availability of the vaccine candidate to the US population when needed, a primary mission of HHS in support of OWS.

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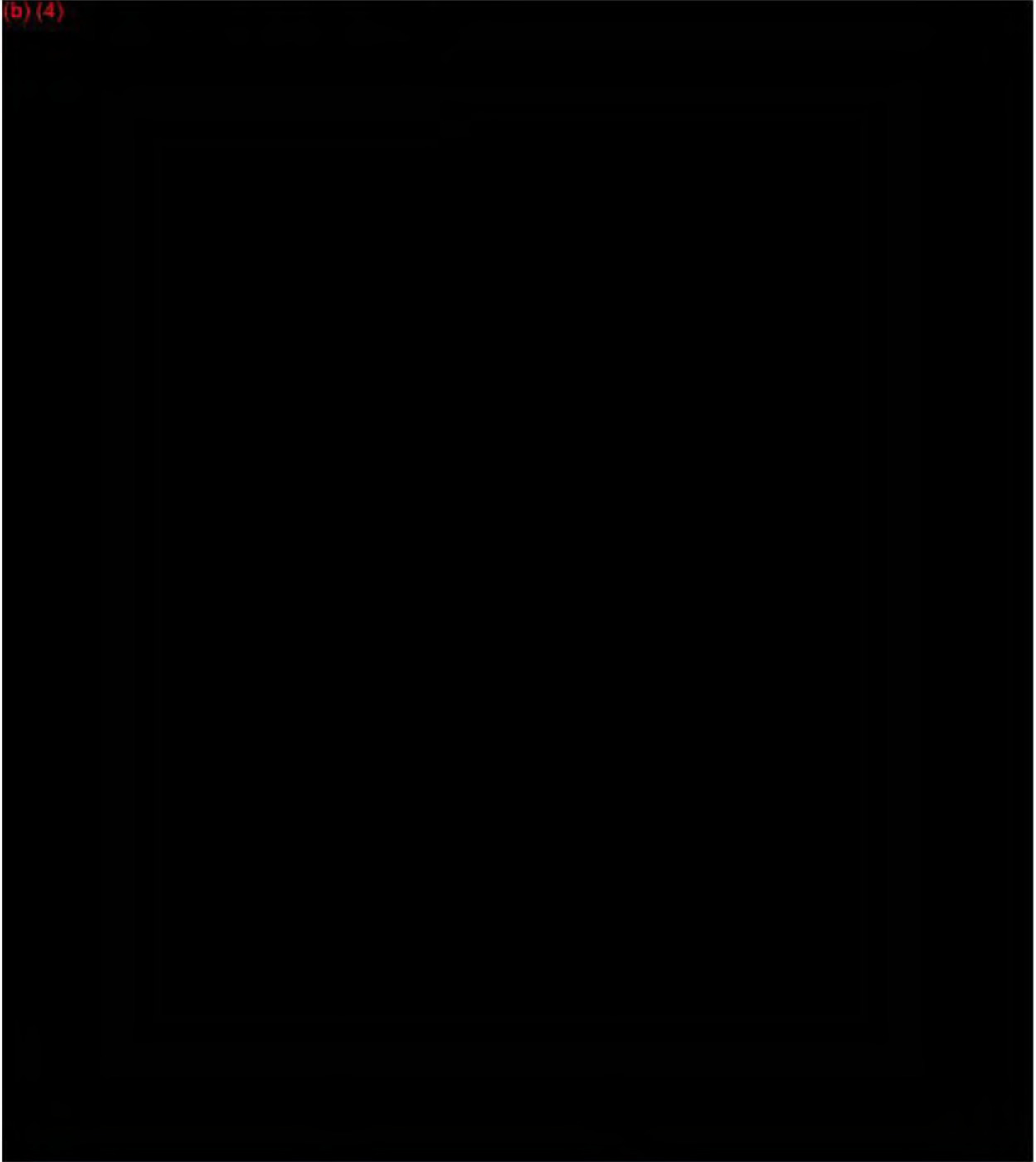
24

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ENCLOSURE 4: PATENT LISTING

(b) (4)



Page 1 of 5

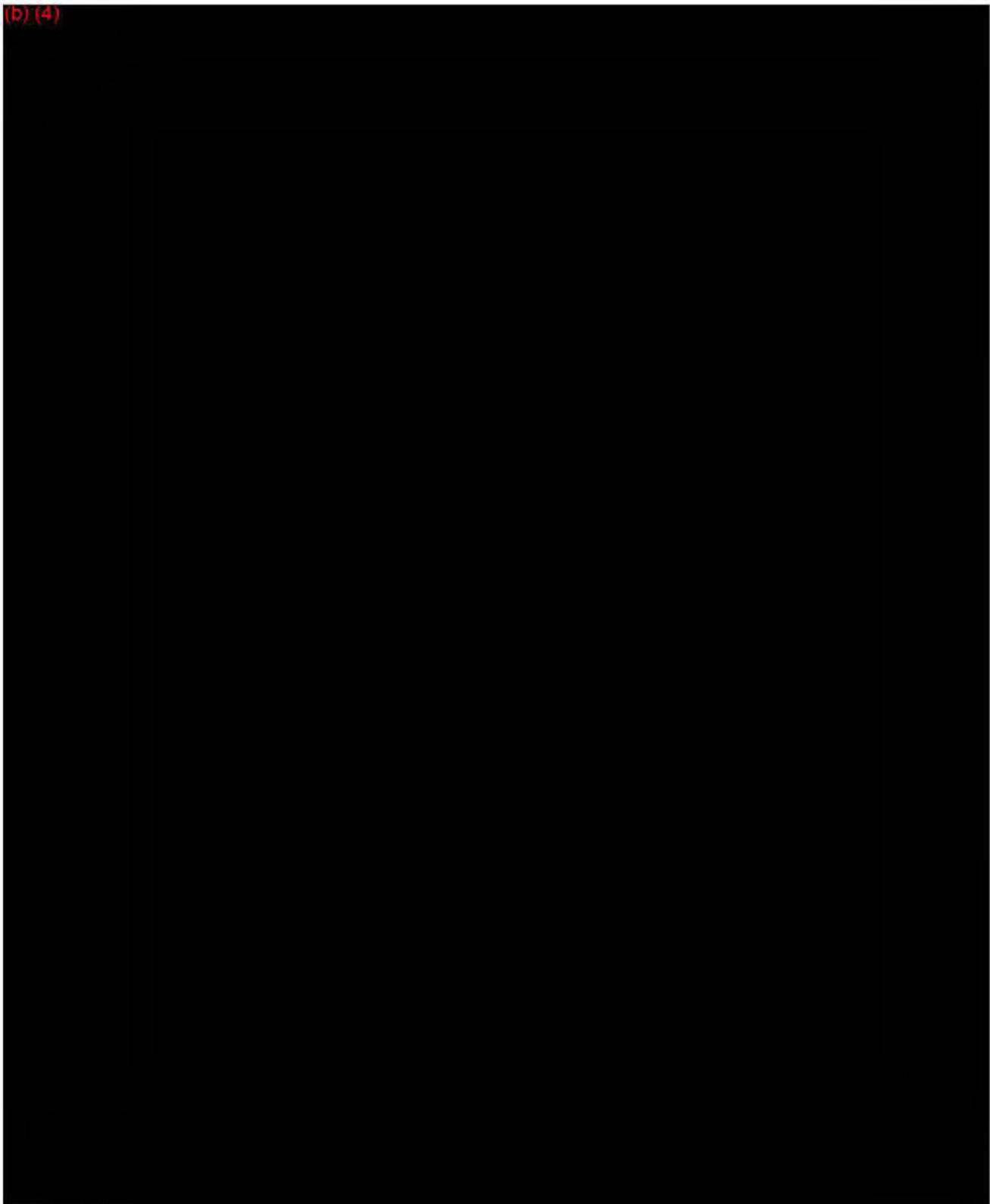
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25

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MULTI-HHS-NIAID-20-2551, 20-2560, 20-2568-A-000028

(b) (4)



Page 2 of 2

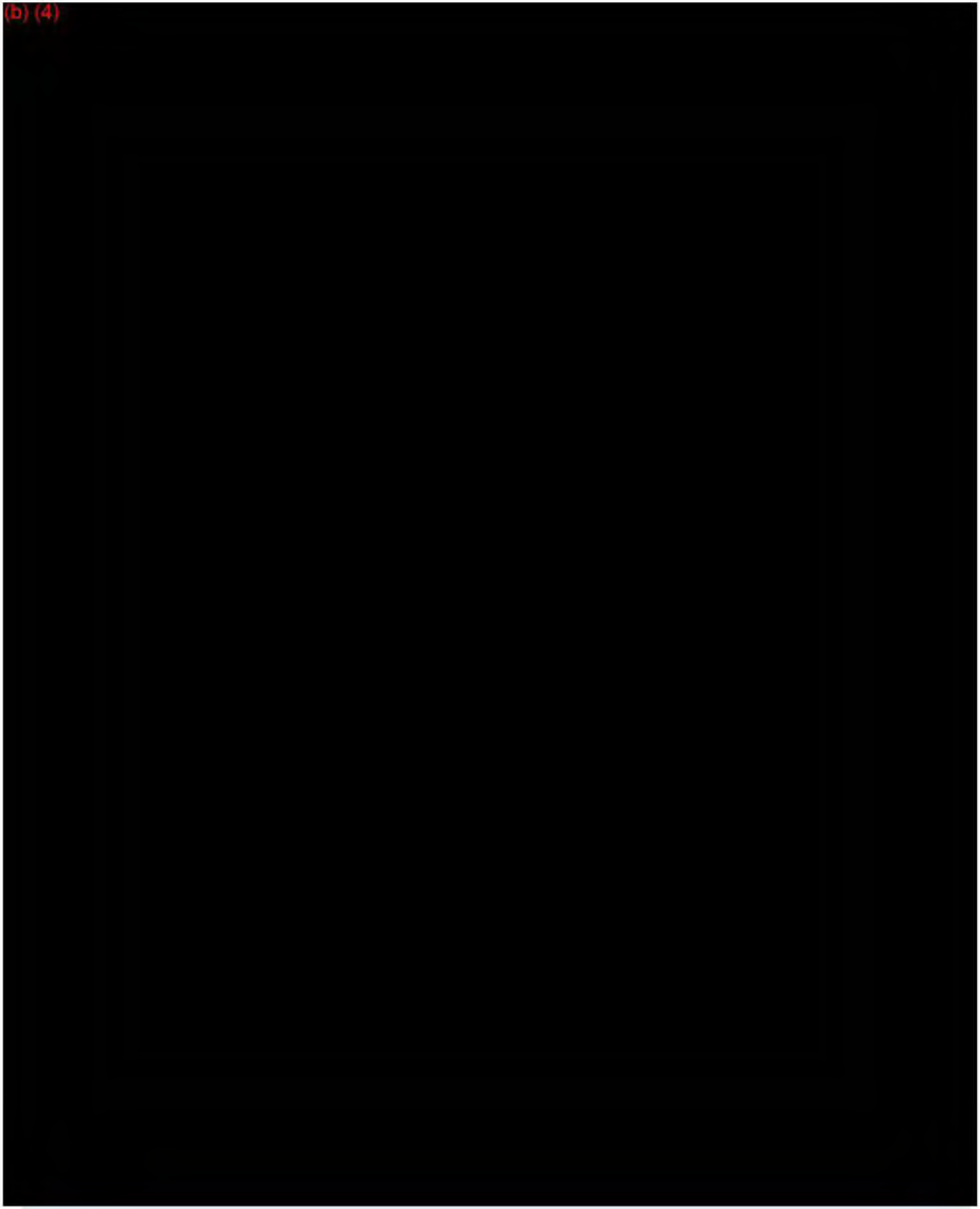
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26

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MULTI-HHS-NIAID-20-2551, 20-2560, 20-2568-A-000029

(b) (4)



Page 3 of 5

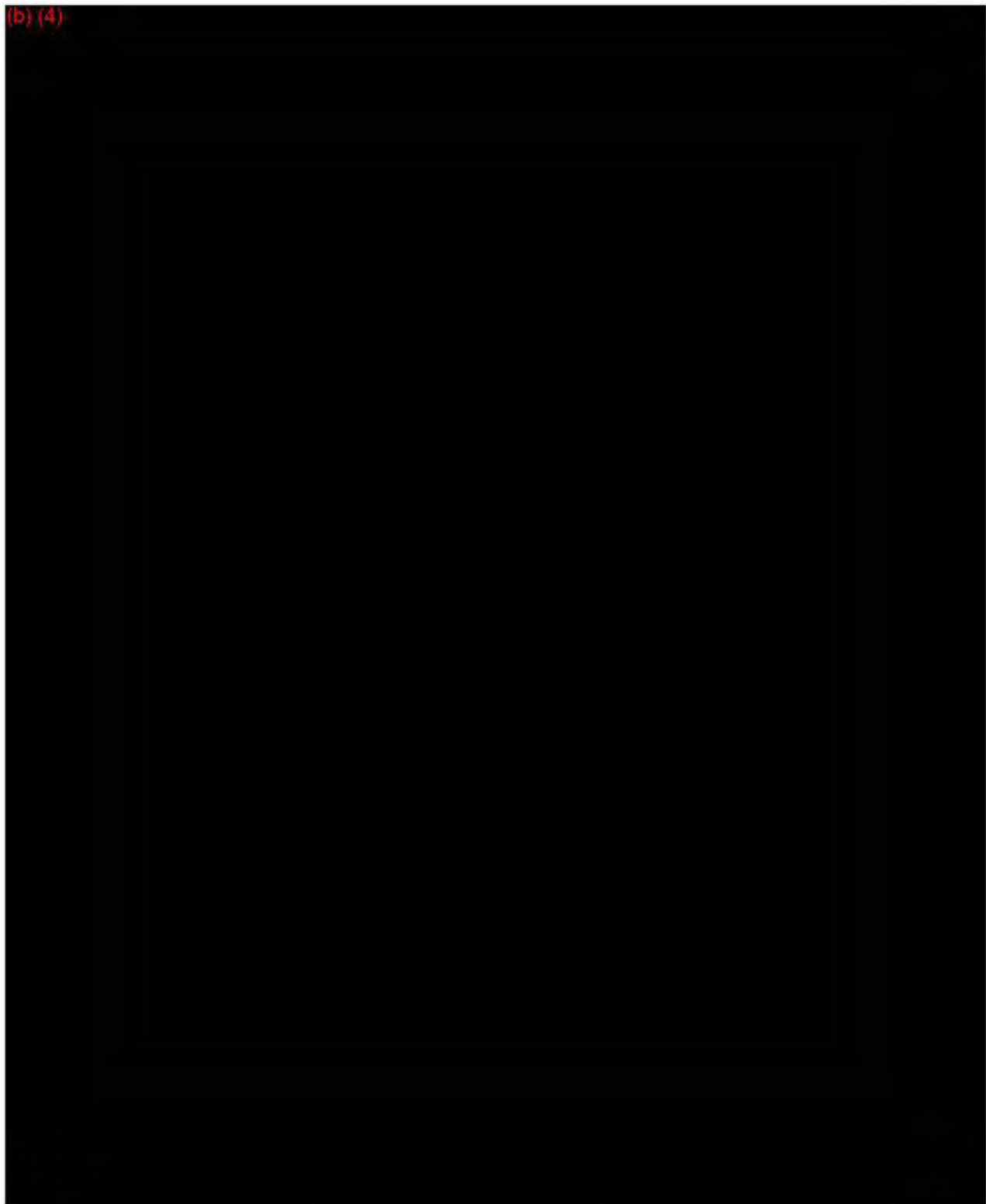
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27

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MULTI-HHS-NIAID-20-2551, 20-2560, 20-2568-A-000030

(b) (4)



Page 4 of 5

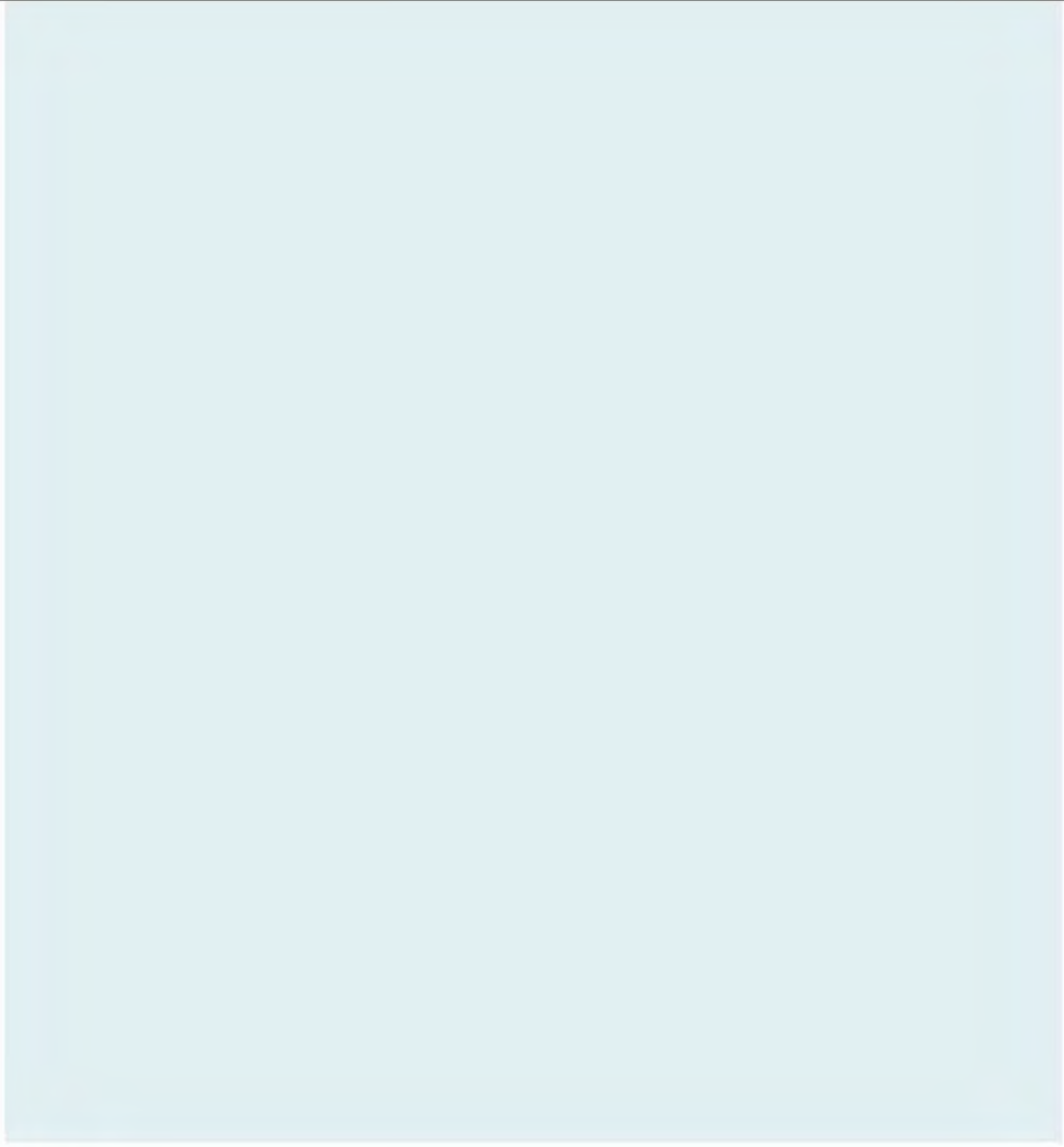
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28

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MULTI-HHS-NIAID-20-2551, 20-2560, 20-2568-A-000031

(b) (4)



Page 5 of 5

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29

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MULTI-HHS-NIAID-20-2551, 20-2560, 20-2568-A-000032

UNDEFINITIZED PROJECT ACTION

MCDC2011-001 is a Cost Plus Fixed Fee (CPFF) Agreement that will be awarded under W15QKN-16-9-1002 (hereinafter "Agreement"). Due to urgency concerns, this Undefinitized Project Action (UPA) is being issued to Novavax, Inc. (hereinafter "Contractor") for Rapid (WF10) Advanced Research & Development to Large Scale Manufacturing of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus. The following is hereby incorporated as part of this Agreement.

1. DEFINITIZATION:

- a) This Agreement covers a CPFF UPA that awards prototype project MCDC2011-001. The Contractor agrees to promptly begin negotiating with the Agreements Officer on the terms of a definitive Agreement for the project, which will include: (1) all mutually agreeable terms and conditions related to this Agreement, and (2) all other terms and conditions required by law. The Contractor will be required to submit a qualifying cost proposal with all necessary supporting documentation, in order to allow for a full evaluation of costs.
- b) The schedule for definitizing this Agreement is as follows:
 - i. Receipt of Qualifying Proposal: 10 September 2020
 - ii. Estimated Start of Negotiations: 01 October 2020
 - iii. Estimated Date of Definitization: 09 December 2020
- c) If a definitive Agreement is not finalized to supersede this UPA by the target date in paragraph 2(b)(iii), or within any extension granted in writing by the Agreements Officer, the Agreements Officer may, with the approval of the Army Contracting Command-New Jersey, Senior Contracting Official, unilaterally determine a fair and reasonable price. This determination is subject to Contractor appeal, as provided for in the Disputes article of W15QKN-16-9-1002, but the Contractor shall not cease performance of this Agreement while proceeding through the dispute process.
- d) After the Agreements Officer's determination of a fair and reasonable price, the Agreement shall be governed by all of the terms and conditions of the definitive Agreement. Furthermore, all the terms and conditions of this UPA shall continue in effect, except for those that by their nature apply only to UPAs.
- e) The Government and Contractor agree that this UPA will include a ceiling in the amount of \$1,600,434,522.00. This ceiling may be adjusted only by the written agreement of both parties.

2. PAYMENT OF ALLOWABLE COSTS BEFORE DEFINITIZATION:

Prior to definitization of this Agreement, the Government will reimburse the Contractor for all allowable and allocable costs up to 50% of the approved Not-To-Exceed (NTE) Price of \$1,600,434,522.00. At any time before a payment, the Agreements Officer may have the Contractor's invoices or vouchers audited. Any payment may be (1) reduced by any amounts found by the Agreements Officer not deemed authorized in accordance with the Statement of Work, or (2) adjusted for overpayments made on preceding invoices or vouchers.

3. LIMITATIONS ON OBLIGATIONS:

The Government will not obligate more than 50 percent of the NTE Price before definitization.

4. LIMITATION OF GOVERNMENT LIABILITY:

- a) In performance of this Agreement, the Contractor is not authorized to make expenditures or incur obligations exceeding \$800,217,261.00 dollars.
- b) The maximum amount for which the Government shall be liable if this Agreement is terminated is \$800,217,261.00 dollars.

5. EXECUTION AND COMMENCEMENT OF WORK:

Upon acceptance by both parties, the Contractor shall proceed with performance of the Statement of Work, including the purchase of any necessary materials.

ARTICLE XVII. SECURITY & OPSEC

The below language shall be used as Paragraph 6 of Article XVII in Novavax's 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.



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

1

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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)

for the prevention of COVID-19 (b) (4)

for the prevention of COVID-19 (b) (4)

(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.

3

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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)

5

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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:

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.

8

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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

9

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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

10

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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

11

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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)

12

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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)

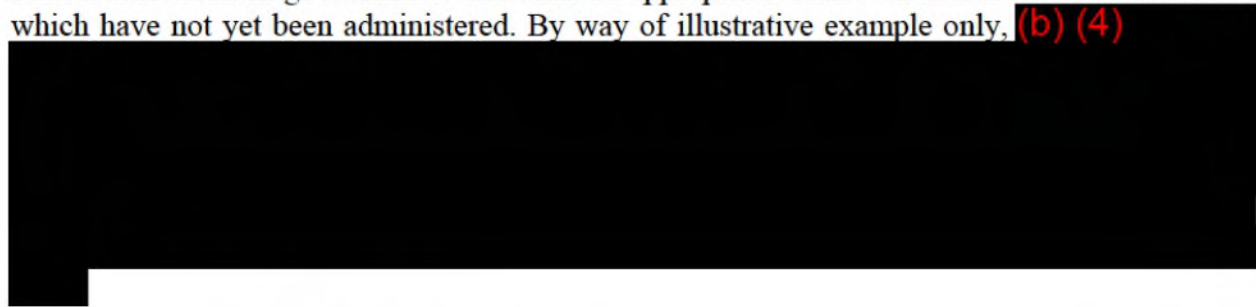
** Quality Management Plan. Pfizer will, (b) (4)

provide a quality management plan (b) (4)

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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)



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)



(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

17

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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

18

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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

19

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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)



20

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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.

22

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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)

23

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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	• 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	• 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	• 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	• identification and marking of sensitive information • access control • storage of information • document control procedures • retention/ destruction requirements
Information Technology/Cyber Security Policies and Procedures	• 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

	• system document control • system backup • system disaster recovery • incident response • system audit procedures • property accountability
2. Site Security Master Plan 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.	
3. Site Threat / Vulnerability / Risk Assessment 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.	
4. Physical Security Description:	
Closed Circuit Television (CCTV) Monitoring	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	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	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	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.

	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	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	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	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	a) Conduct new employee security awareness training. b) Conduct and maintain records of annual security awareness training.
Security Management	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	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	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	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	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	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	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. 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.



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

REPLY TO
ATTENTION OF

30 July 2020

Army Contracting Command – New Jersey
ACC-NJ, Building 10
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 Undefined “Adjuvanted Recombinant COVID-19 Vaccine Development” Sanofi Pasteur, Inc. (Sanofi)

REF: Sanofi Request for Technical Direction Letter, RPP 20-11 under OTA W15QKN-16-9-1002 for Objective PRE-20-11, dated 30 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 Sanofi as the awardee. The Government requests that a combination Cost/Firm-Fixed Price Project Agreement be issued to Sanofi 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).

The Government received the undefinitized Rough Order of Magnitude (ROM) proposal update on 24 July 2020, and reviewed the costs and documentation accordingly. Based upon the acceptable update of Sanofi’s proposal for “Adjuvanted Recombinant COVID-19 Vaccine Development” 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 ROM that has been analyzed and concurred to by the Government, you are hereby directed to issue a Undefinitized Project Agreement to Sanofi for the subject project. The total project value will be determined fair and reasonable via a subsequent modification to the project agreement.

The total approved cost to the Government for this effort is not to exceed (b) (4). The break-out of the costs is as follows: \$1,769,013,470 to perform project efforts included in the SOW (b) (4). (b) (4) This modification obligates the full amount of fee/rate ATI would be due under normal circumstances. Should the Government determine that a special allocation rate is applicable to projects in support of Operation Warp Speed, the Government will unilaterally deobligate the funds which represent the delta between ATI’s standard rate and the agreed upon special allocation rate. While the identified amounts are incorporated into the OTA, they are subject to the limitations in the undefinitized addendum. Specifically, member funding is limited to 50% of the member ceiling. The COVID-19 work shall be tracked separately using the funding obligated via modification P00078. It is noted

that this project has a base period of performance of forty-eight (48) months, with a projected completion date of 30 September 2024.

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.

As this project agreement is undefinitized, please see Attachment 2 of this letter for conditions to be included in the project agreement.

The Sanofi Project Agreement shall contain the following language:

“The contractor consents and agrees that while this Agreement is executed between Sanofi and MCDC, because of the involvement of the Government in selection, award, and the funding process, and because the work of the contractor directly benefits the Government, the contractor is in direct privity with the Government and agrees to resolve any dispute not otherwise resolved through operation of the Disputes clause directly with the Government in a competent court of Federal jurisdiction.”

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

Attachments:

Attachment 1: MCDC RPP 20-11 Sanofi SOW

Attachment 2: UPA Addendum - MCDC RPP 20-11 – Sanofi

**Statement of Work
For Adjuvanted Recombinant COVID-19 Vaccine Development**

RPP #: 20-11

Project Identifier: MCDC2011-005

Consortium Contractor: Sanofi Pasteur

Title of Proposal: Adjuvanted Recombinant COVID-19 Vaccine Development

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

The overall objective of this contract is to advance the development of a vaccine prototype as a countermeasure for the prevention of Novel Coronavirus COVID-19. A COVID-19 vaccine prototype development is required jointly by the US Department of Defense and the Department of Health and Human Services. The objective of the project is to quickly and thoroughly develop and test an effective vaccine for licensed application against COVID-19 and provide rapid manufacturing capability of vaccine doses to serve public health and national security needs. In addition to protecting the American public, prevention of highly contagious and virulent COVID-19 outbreaks is a crucial force protection effort, facilitating US Armed Forces deployed, at sea, or CONUS in maintaining the required OPTEMPO and executing all assigned joint mission essential tasks. This project is for the Rapid Advanced Research and Development (ARD) and Large-Scale Manufacturing of a state-of-the-art vaccine against Pandemic COVID-19.

1.2 Scope of the Prototype Project

This is a prototype project, consistent with 10 USC 2371b, because the Contractor will 1) develop an adjuvanted recombinant vaccine to evaluate efficacy in the generation of immunity antigens against COVID-19 viral infections (**Product Development**) and 2) rapidly expand its manufacturing capability to accomplish production at a scale necessary to respond to the pandemic (**Manufacturing Capability**). The manufacturing described below will comply with Current Good Manufacturing Practices (cGMP) regulations at 21 CFR 210 and 211. Production and distribution will comply with the Drug Supply Chain Security Act where applicable, taking into account FDA's regular guidance for the public health response. The following describes the prototype project in greater detail:

Sanofi Pasteur will achieve obtaining Emergency Use Authorization (EUA) under requirements to be determined by FDA, and/or a reasonable chance of moving to Phase III clinical trials by January 2021 with the goal of achieving FDA licensure in 2021 for Adults and Pediatric indication by September 2023. The objectives encompass all development plans and efforts, including manufacturing as part of this prototype project. Sanofi Pasteur will demonstrate capability to manufacture, stockpile, and distribute large quantities of MCM to respond when needed. Sanofi Pasteur will perform non-clinical and clinical advanced development and/or at-scale prototype manufacturing and fill-finish of a SARS-CoV-2 Medical Countermeasure (MCM). Manufacturing shall take place in a US-based facility, with assurance of sourcing of adequate material for production. Production shall occur using cGMP validated manufacturing process, fully compliant with 21 CFR 210 and 211, for bulk drug substance and fill and finished drug product, with a ramp-up capacity that provides doses sufficient for the government to vaccinate the US population. The provision of vaccine doses will be compliant with applicable provisions of the Drug Supply Chain Security Act (DSCSA) Sections 581-585 of PL 113-54 (Nov 27, 2013).

The scope of this prototype project includes clinical material manufacturing, preclinical, clinical, regulatory, and industrialization activities that fall into the following areas: non-clinical efficacy and toxicity studies; phase III clinical activities; manufacturing scale up activities; and all

associated regulatory, quality assurance, management, and administrative activities. The scope of the prototype project is broken into the following phases, which are discrete work segments:

- I. Regulatory Planning
- II. Clinical Materials Manufacturing
- III. Non-Clinical Activities
- IV. Clinical Development
- V. Commercial Scale Drug Substance
- VI. Commercial Scale Formulation and Filling
- VII. Management and Reporting

1.3 Follow-on Production

In accordance with 10 U.S.C.2371b(f), and upon a determination that the Product Development or Manufacturing Capability portions of the prototype project for this transaction have 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. The prototype vaccine candidate will undergo Clinical Studies through Phase III ultimately supporting FDA licensure of the vaccine and cGMP manufacturing process.

This prototype project will be successfully completed if the Contractor meets the key technical goals of the project, as listed within this document, meets the success metrics established by this agreement or, or at the accomplishment of particularly favorable or unexpected results that justifies transition to production. Key Technical goals include, but are not limited to, achieving regulatory milestones with the US Food and Drug Administration (FDA) such as emergency use authorization (EUA) under 564 of the FD&C Act or a biologics licensure granted under Section 351(a) of the Public Health Service Act, The manufacturing of 100,000,000 doses will demonstrate the success of the Manufacturing Capability portion of the prototype effort.

This prototype project includes unpriced options for follow-on production. During the performance of the prototype project, the Government, Project Agreement Holder and (b) (4) will negotiate the scope, price and timing of production. Any pricing for the (b) (4) adjuvant shall be based on commercial item terms and price. If the prototype project is successful, the Government may then enter into follow-on production by executing these options through a separate stand-alone production agreement. The Follow-on production is estimated to be sufficient quantities of drug product to vaccinate up to 300,000,000 people, based on a two-dose regimen (additional 500M doses).

1.4 Caveats and Risks

Due to the rapid development of this vaccine program and the multiple unknowns associated with SARS-CoV-2 and the pandemic the following items (but not limited to) are recognized as potential impacts on this clinical development plan:

- Certain assumptions are based on US Government contracting with partners and suppliers and those contracts may impact this timeline.
- Sanofi recognizes the proposed clinical development plan in the SoW is based on currently available information, could change as prototype development progresses, that this could result in changes to the SoW and project costs. These changes will be agreed to between both parties and the SoW will be modified.

1.5 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 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 (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) Contractor’s performance of this Agreement falls within the scope of the “Recommended Activities” for responding to the COVID-19 public health emergency, to the extent it is in accordance with Section III of the PREP Act Declaration; and
- (iii) Contractor is a “Covered Person” to the extent it is a person defined in 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 acquisition as long as Contractors activities fall within the terms and conditions of the PREP Act and the PREP Act Declaration.

2.0 APPLICABLE REFERENCES

21-CFR-600 through 680
21 CFR 210, 211 (Current Good Manufacturing Practices or “cGMPs”)
21 CFR 312 (Investigational New Drug Application)
21 CFR 50, 54, and 56 (Human Subject Protections)
P.L. 115-91 (Expedited Approval for Military Medical Priorities)

3.0 REQUIREMENTS

3.1 Regulatory Planning

The Contractor will target the FDA approval of an adjuvanted recombinant SARS-CoV-2 protein vaccine to be presented in multi-dose vials. The Contractor will submit a new vaccine application to be developed for individuals 6 months of age and older. Owing to the accelerated timelines of a COVID-19 vaccine development program, the Contractor will initially pursue an indication in adults only with first approval in healthy adults ≥ 18 years of age, including the elderly population, as well adults with pre-disposing co-morbidities. The Contractor will initiate pediatric studies following the successful demonstration of vaccine efficacy in the adult pivotal Ph III efficacy trial and registration in the pediatric population will be proposed as the

supplement to the initial approval. The Contractor will request CBER agreement to defer vaccine development in the pediatric population to post-licensure.

The Contractor already shared with the Center for Biologics Evaluation and Research (CBER) the Phase III concept protocol for the safety and efficacy study in adults as part of the pre-IND interaction in May 2020 and received written answers on June 3rd. The Contractor will submit the pre-final protocol with the main design features except for the dose & dosing schedule will be submitted to the FDA at least 60 days before the initiation of the Phase III trial in an amendment to the corresponding IND. The final protocol cannot be submitted 60 days in advance as the Contractor will not know the final dose or dosing schedule. The final approved protocol should have also been reviewed and approved by the regulatory authorities of the countries selected for this clinical trial before the initiation of the trial.

The Contractor will request expedited CBER review time to allow a seamless progression to Phase III following Phase I/II key data availability (Safety, Neutralizing antibodies, Cell mediated immunity) currently planned in December/January 2021 and the completion of non-clinical studies performed in parallel to the Phase I/II (Toxicology rabbit study, animal challenge models). The Contractor will negotiate the same accelerated approval of the clinical trial application with the other countries included in this Phase III study.

The Contractor will request “Fast Track” designation by CBER to allow the rolling submission of sections of the BLA as soon as they are completed with an Accelerated Approval, Priority Review or Breakthrough Therapy designation following the submission of the last BLA components.

Post-licensure commitments will be required by the FDA for approval of the vaccine. The requirements will be definitized as directed by the FDA after BLA submission.

3.2 Clinical Materials Manufacturing

The host cell line that has been used for the generation of the recombinant baculovirus expression vector harboring the CoV2 preS dTM gene and will be used as a substrate for the recombinant CoV2 preS dTM protein manufacturing is a serum-free Lepidopteran insect cell line designated expresSF+® (hereafter referred to as “SF+”). The SF+ cell line is maintained in serum-free cultivation medium, Protein Sciences Formulary Medium (PSFM) and is used for the production of Sanofi Pasteur’s licensed Flublok® seasonal influenza vaccine.

The following activities are being performed under an existing HHS contract, and will be completed in preparation for the subsequent work described here:

- Baculovirus Working Virus Bank
- Working Virus Bank Testing
 - Three cell in vitro assay for adventitious viruses
 - Sterility of Working Virus Bank
 - Virus titer to determine WVB potency
 - Verification of the DNA identity of the coding sequence inserted in WVB
 - Western blot to confirm protein identity

3.2.1 Description of Clinical Drug Substance Manufacturing

For cGMP manufacturing of the COVID-19 vaccine for Phase III clinical studies, the licensed Flublok influenza vaccine manufacturing platform (BLA STN 125285) is being leveraged as much as possible. The CoV2 preS dTM Spike protein drug substance manufacturing process itself is still under development, however it will be a hybrid process taking advantage of Sanofi Pasteur's licensed Flublok process and prior work with the manufacture of the SARS-CoV ΔTM S vaccine (IND #14811). (b) (4)

The DS manufacturing process comprises two major process blocks, the Upstream Process (USP), which includes cell culture expansion and protein production in the bioreactor, and the Downstream Process (DSP), which includes separation and concentration of the bioreactor supernatant and purification of the CoV2 preS dTM protein.

The production process for the CoV2 preS dTM will follow the licensed Flublok process from amplification of the WVB until the harvest of the production bioreactor. (b) (4)

Upstream Process Development: The Contractor will conduct upstream process development activities to support vaccine production at the (b) (4). Activities will include:

- Cell Culture Expansion
- WVB Expansion
- Protein Production

Downstream Process: The Contractor will conduct downstream process development activities to support manufacturing at a scale of (b) (4). Activities will include:

- (b) (4)
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3.2.2 Description of Late Phase Clinical Drug Product Manufacturing

Formulation and filling COVID-19 vaccine containing antigen in multi-dose vials at 3 mL fill volume and manufacture the two formulations (5µg and 15µg) supporting the clinical protocol from the Sanofi Pasteur Swiftwater manufacturing site.

- COVID-19 vaccine drug substance material derived from purified recombinant CoV2 preS dTM Protein manufactured under aseptic conditions will be formulated and filled into multi-dose vials
- Following cGMP practices formulate up to 150L drug product which will be filled in building 77 Line 9, or alternate site. Validation of the formulation and filling process will be conducted post clinical manufacturing and part of the concurrent to the commercial manufacturing of the COVID-19 vaccine doses
- Aseptic process development will be required along with change parts for Line 9 to

- support the MDV. The change parts will be C&Q prior to use for manufacturing
- Manufacture required buffer material to be used for the formulation process
- Automated Inspection will occur for the filled containers
- Labelling will occur in B37 can cell pack styled packaging will be used for the finished goods.
- (b) (4)
- Sanofi Pasteur will furnish the necessary services, qualified personnel, materials, supplies, equipment and facilities not otherwise provided by the U.S. Government as needed to manufacture the clinical doses

The Contractor will conduct downstream process development activities to support manufacturing including:

- Formulation
- Filling
- Visual Inspection
- Clinical Labelling and Packaging

3.2.3 Description of Drug Product Testing

3.2.3.1 In-Process Quality Control Sampling - All Antigen specific testing will be at (b) (4). The AQL inspection testing and safety testing will be performed at (b) (4) site using established procedures and acceptance criteria.

3.2.3.2 Stability Testing - For the duration of Stability Testing, the material reserved will be maintained at (b) (4). All unlabeled FCs aside from clinical material or Stability Testing material will be secured at that location under conditions to be determined.

Any reporting of stability results will be done by Sanofi (b) (4).

3.3 Non-Clinical Activities

In addition to studies accomplished under a previously awarded HHS contract, non-Clinical activities will be performed to support Ph III studies and licensure. Some activities are expected to be required to document the vaccine mechanism of action. In vivo studies will be performed to explore the biomarkers for protection and the persistence of the immune responses.

In vitro studies are proposed to evaluate the role of neutralizing antibodies in an in vitro lung model in order to assess the potential for antibody-dependent enhancement (ADE).

3.3.1 Immunogenicity study to explore mechanism of action / biomarkers of protection (study 7): In a permissive rodent model, such as human ACE2 Receptor expressing mice, the role of the Ab and the CD4/CD8 T cells in protection will be explored. A mouse model would allow to study the role of both the Ab and the cellular responses. If the human ACE2 mice were not suitable to assess protection, other models such as hamster or ferrets could be used to study the role of Abs.

3.3.2 Immunogenicity study to explore Ab persistence/duration of immune response & protection (study 8): The longevity of the immune responses (Ab, T and B cells), and the

duration of protection will be analyzed in a CoV2-permissive animal model such as ferrets, hamsters or NHPs. These species have a sufficient half-life to allow for Ab decay.

3.3.3 Evaluation of the vaccine antibody enhancement in vitro: The Abs elicited by the vaccine in animal models or humans, will be assessed in vitro on a human lung cell model developed at VxD. This system will allow to measure both the neutralization of viral entry through blockade of S attachment and fusion and the potential facilitating role of Ab through Fc-dependent viral entry and infection.

3.3.4 Developmental & Reproductive Toxicity Testing (DART): Considering the target age range of the vaccine candidate, and to support the vaccination of Women of Child Bearing Potential (WOCBP), it is considered to conduct a combined DART study to evaluate female fertility, as well as any potential effect of the vaccine on mating performance, on all stages of embryo-fetal development and on the post-natal development of the pups (over the lactation period). These potential effects could be evaluated in a single study plan, designed in compliance with applicable WHO guidelines on preclinical testing of adjuvanted vaccines and vaccine adjuvants (2005, 2013). The study will be most likely carried out at Charles River, Montreal, Canada, test facility and conducted in compliance to Good Laboratory Practices (GLP) regulations. The DART study can be performed in parallel of Phase III clinical study, using Phase III clinical batches.

As for the standard repeated dose toxicity study, the rabbit will be selected as the toxicity species. Each injection will consist of one intended human dose and dose volume (0.5 mL). The number of injections would be as follows:

- Premating period: 2 injections in female parent rabbits: 24 days and 10 days before mating
- Gestation period: 3 injections of the dams (GD6, GD12 and GD27)

During the study, the immune response to the test vaccine will be determined through ELISA testing in:

- In all dams per sub-group during pretest, 3 days before the start of mating, and either on Day 29 post-coitum or on Day 35 post-partum
- In all fetuses from all dams in the caesarean sub-group on G29 (pool fetus sera)
- In all pups from all dams in the littering sub-group on L35 (not pooled)

The study group composition is summarized in 3.3.4 below:

Table 3.3.4 DART Study Group Composition

Study Gps	Study Subsets	Treatment	Dose-level (Dose-volume) per injection	Total # of injections	# of animals	Date of sacrifice
1	C-subset	Control (0.9%NaCl)	1HD (0.5 mL)	5	25	Day 29 <i>p.c.</i>
	L-subset			5	30	Day 35 <i>p.p.</i>
2	C-subset	Antigen alone (Protein S = Ag)	1HD (0.5 mL)	5	25	Day 29 <i>p.c.</i>
	L-subset			5	30	Day 35 <i>p.p.</i>
3*	C-subset	Ag + AF03	1HD (0.5 mL)	5	25	Day 29 <i>p.c.</i>
	L-subset			5	30	Day 35 <i>p.p.</i>
4*	C-subset	Ag + (b) (4)	1HD (0.5 mL)	5	25	Day 29 <i>p.c.</i>
	L-subset			5	30	Day 35 <i>p.p.</i>

*HD: Human Dose; C-subset: caesarean subset; L-subset: littering subset; p.c.: post-coitum; p.p.: post-partum; *inclusion of both groups needs to be confirmed*

3.4 Clinical Development

The development plan targets the FDA approval of an adjuvanted recombinant SARS-CoV-2 vaccine for pandemic use with antigen to be presented in unit dose or multidose vials and adjuvant presented in multidose vials. The vaccine will be developed for adults. Pediatric development will be performed, although is not planned to be completed prior to licensure in adults.

As part of a funded Task Order from BARDA, a Ph I/II clinical trial in adults 18 years of age and older to evaluate safety and immunogenicity of different recombinant protein vaccine formulations with two different adjuvants (AF03 and (b) (4)) is planned. This Ph I/II trial will evaluate two different doses of recombinant protein antigen administered as either a single vaccination or two vaccinations 21 days apart. Immunogenicity assessment includes Neutralizing antibodies to wild-type SARS-CoV-2, binding antibodies measured by ELISA & cellular immune responses for Th1/Th2 immune response characterization. SP is planning to conduct an analysis on data collected up to 21 days after the final vaccination and submit a limited data package for FDA review prior to progression to later phase clinical development. Supplemented by non-clinical studies, this safety and immunogenicity data will be the basis for selecting one of the formulations to progress to the later stage of clinical development.

The Contractor will conduct 3 clinical trials in this proposal as part of the later stage of clinical development:

- VAT02 - a pivotal Ph III efficacy trial in adults 18 years of age and older for registration, with interim analyses that may result in early demonstration of efficacy and subsequent licensure.
- VAT03 - Safety and immunogenicity trial in children 6 months to 17 years of age to support licensure in the pediatric population. This safety and immunogenicity trial to seek approval in the pediatric population is dependent on endorsement by the Regulatory Authorities. Given the lack of an established pathway for licensure in this population, it is still possible that an efficacy trial may be required by the regulators.
- VAT04 - Lot-to-lot consistency trial in adults, if required by Regulatory authorities in the event that pharmaceutical bio-comparability data is considered insufficient.

The Contractor will include the selected candidate vaccine formulation (b) (4) in the Ph III efficacy trial in which it will be compared against placebo. A placebo-controlled trial may not be appropriate if a vaccine is approved and available in the countries and at the time of conduct of the trial. If an approved vaccine was available, three alternative paths to licensure will be considered: 1) The possibility of performing a safety and immunogenicity study aiming at demonstrating that the immune responses with Sanofi Pasteur's vaccine are comparable to those of the licensed vaccine, in the event there is a suitable biomarker accepted by Regulatory authorities; 2) The possibility of still conducting the efficacy study but in geographies where a vaccine is not licensed/available; 3) The possibility of performing a larger study aiming at demonstrating non-inferior efficacy against the licensed vaccine. Recognizing these three

scenarios as possibilities, the expanded narrative in section 3.4.1. focuses on the assumption that a placebo-controlled trial with the objective of demonstrating efficacy will be conducted.

3.4.1 Clinical Plan for Adults and Elderly – Phase III Efficacy Study

The Phase III trial in adults is designed to support regulatory licensure based on statistically powered efficacy endpoints and an adequate safety database. The dose of the recombinant protein antigen and whether it is administered as a single injection or two injections 21 days apart will be determined based on safety and data on neutralizing antibodies observed in the Phase I/II study and on aggregated data from non-clinical studies. For the purposes of this proposal it is assumed that the study will require participants to receive a schedule with 2 injections.

VAT02 will be a Phase III, randomized, modified double-blind, placebo-controlled, multicenter study to be conducted in 34,656 adults 18 years of age and older to evaluate the efficacy, safety and immunogenicity of SARS-CoV-2 recombinant protein with (b) (4) versus a placebo. The study groups and sample size are described in Table E.1.1 below.

(b) (4)



(b) (4)



(b) (4)



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3.4.2 VAT03 - Clinical Plan for Pediatric Development

Assuming success in the demonstration of satisfactory safety and efficacy in adults in the pivotal Ph III study, a clinical trial for licensure in the pediatric population will be initiated. It is assumed that the pediatric trial will be conducted after initial approval in the adult population.

This will be a randomized, modified double-blind, placebo-controlled trial to assess safety and immunogenicity in children 6 months to 17 years of age. Approximately 350 participants will be enrolled and randomized in a 6:1 ratio to receive 1 or 2 injection(s) of either the investigational product (SARS-CoV-2 Recombinant Protein investigational study vaccine with (b) (4) or placebo (300 participants in the vaccine group and 50 participants in placebo group). For the purposes of this proposal it is assumed all subjects will require 2 vaccinations. The enrollment will be stratified by age groups (6mo-35mo of age, 3-8 years of age and 9-17 years of age). The duration of the follow-up would be 1 year with safety follow-up conducted over the duration of the study period.

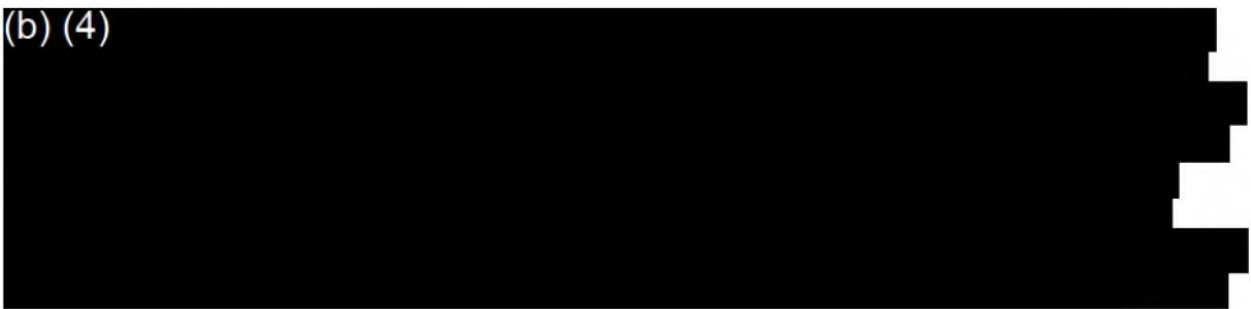
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3.4.3 VAT04 - Clinical Plan for Lot-to-Lot consistency

A safety and immunogenicity trial in adults is planned to demonstrate comparability of three lots of manufactured product if required by Regulatory authorities based on availability and robustness of pharmaceutical bio-comparability data. It is assumed that participants will be administered two injections.

This will be a randomized, modified double-blind trial to assess safety and immunogenicity in adults 18 years of age and older. The primary objective would be to demonstrate equivalence of immune response across all three lots for the vaccine candidate. Participants would have blood samples collected at D1 and D43 for assessment of neutralizing antibodies and binding antibodies by ELISA to the Spike protein to address the primary objective.

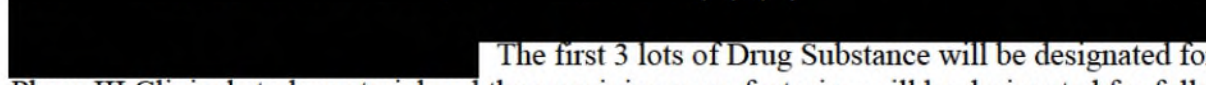
(b) (4)



3.5 Commercial-Scale Drug Substance

The Drug Substance Manufacturing Process will be locked concurrently with the Phase III clinical manufacturing process. Phase III clinical manufacturing will occur (b) (4)

will commence with commercial production, at risk. (b) (4)



The first 3 lots of Drug Substance will be designated for Phase III Clinical study material and the remaining manufacturing will be designated for follow on production.

3.5.1 Commercial-Scale Drug Substance Manufacturing Process will be as outlined in section 3.2.

3.5.2 Technology Transfer

(b) (4)



(b) (4)

(b) (4)

(b) (4)

A comparability study will be conducted, concurrently with PPQ batch manufacturing, to demonstrate the product and process comparability between the two (2) Drug Substance manufacturing locations.

3.5.3 Analytical Transfer

In order to streamline the transfer activities and to minimize the changes between (b) (4) sites, one (1) analytical testing reference site will be utilized. (b) (4)

The exceptions to this strategy are time sensitive tests (i.e. microbial) and in-process controls (IPCs). These tests will be transferred to the Drug Substance CMO following standard analytical transfer methodology.

3.6 Commercial-Scale Drug Product

Formulation and filling COVID-19 vaccine containing antigen in multi-dose vials at 3 mL fill volume and deliver 100 M doses to the US Government (b) (4)

- COVID-19 vaccine drug substance material derived from purified recombinant CoV2 preS dTM Protein manufactured under aseptic conditions will be formulated and filled into multi-dose vials.
- Following cGMP practices formulate up to 500 L drug products (b) (4)
Validation of the formulation and filling at commercial scale will be conducted concurrently to the commercial manufacturing.
- Aseptic process development will be required along with change (b) (4) support the filling of the MDV. The change parts will be C&Q prior to use for

manufacturing.

- Manufacturing of buffer will be required to be used for the formulation process.
- Automated Inspection will occur for the filled containers.
- Labelling will occur (b) (4) in cell pack styled packaging will be used for the finished goods.
- (b) (4)
- Sanofi Pasteur will furnish the necessary services, qualified personnel, materials, supplies, equipment and facilities not otherwise provided by the U.S. Government as needed to fill the required number of doses.

Assumptions Regarding Manufacturing Requirements

- Drug substance yields are (b) (4) (Sanofi Pasteur assumes risk of achieving targeted yield)
- Cycle time of (b) (4)
- Fuji capacity (b) (4)
- Tech transfer (b) (4)
- Start of Commercial DS in PR (cell amplification as soon as bioreactors free up from phase III production)
- (b) (4)
- No serialization at the vial level
- (b) (4)
- Specific packaging requirements for final Finished Goods (antigen and adjuvant) will be determined through discussion with USFDA and the agreement will be modified to reflect those costs, if required

3.6.1 Formulation

The antigen formulations will be manufactured at (b) (4) site using the purified recombinant CoV2 preS dTM Protein along with (b) (4). All formulation activities will follow SP standard operating procedures under cGMP conditions. Formulation of the purified recombinant CoV2 preS dTM Protein will be done to support the 20 µg /mL (5µg/dose) protein content.

3.6.2 Filling

The finished good vaccine Final Containers will be filled (b) (4) following qualified aseptic filling procedures under protocol, adhering to cGMP. SP will target fill quantities in support of the 500L formulation batch size requirements. Final Container fill volume will target a 3.0 mL fill volume.

3.6.3 Inspection

The Filled final containers will be subjected to individual automated inspection per established SP procedures to verify conformity to specification and to identify, remove, and categorize any non-conforming Filled final containers.

3.6.4 In-Process Quality Control Sampling

All Antigen specific testing will be (b) (4) The AQL inspection testing and safety testing will be performed (b) (4) using established procedures / acceptance criteria.

3.6.5 Stability Testing

For the duration of Stability Testing, the material reserved will be maintained (b) (4) All unlabeled FCs Stability Testing material will be secured at that location under conditions to be determined.

3.6.6 Documentation / Reporting

SP will provide regulatory documents to support an IND (IB, LOA to cross reference BMF, stability, Module 3 CMC documents, etc.).

3.6.7 Production and Storage of 100 million doses of Drug Product Final Container

Long-lead time materials will be ordered to ensure that drug substance production can start in (b) (4)

The estimate includes any acceleration fees that might be needed to ensure suppliers deliver within the required time frame.

In order to meet the delivery schedule for the 100 million proposed in the table below, selection of the dose at which the drug substance will be made at risk based on non-clinical data in consultation with BARDA and Operation Warp Speed Leadership so that fill finishing of doses can be initiated (b) (4). The pricing proposal is based on the assumption that a 5µg dose will be selected. If a decision was made not to initiate formulation and fill finish of the doses based on the available data, drug substance would continue to be produced but the delivery schedule for drug product would be delayed.

(b) (4)

(b) (4)

3.6.8 Shipping Demonstration

In coordination with the Government, Sanofi will conduct a demonstration of the vaccine (adjuvant + antigen) shipping process prior to the first delivery of doses at a time mutually agreed by the Parties. As set forth in Section 4.0 (Deliverables), Sanofi 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. For

planning purposes, the Government intends to have the vaccine shipped to [USG designated Distribution Centers and/or USG designated administration sites].

3.7 Management and Reporting

3.7.1 Project Management

As in the numerous projects Sanofi Pasteur has undertaken in partnership with HHS/BARDA since 2004, SP will assign a Principal Investigator (PI) responsible for leading the effort of the project team representatives to achieve the desired outcome. The project team Contractors are responsible for the activities of their respective functional areas. The PI directs the project team Contractors using the work plan, project schedules, and progress reports. The PI communicates the project objectives to the project team representatives and keeps the team tasks within the scope of the project. The PI facilitates communication and resolves conflict among project team Contractors and negotiates for any resources required. The PI works to see that the overall objective of the project is delivered on time, on budget, and with the right level of quality. The PI updates the Executive Sponsor on the progress of the project and any obstacles in achieving project objectives. The PI will have an assigned Project Manager (PM) who, along with Sanofi Pasteur Finance, will track activities and spending according to a Work Breakdown Structure (WBS). Sanofi Pasteur will share the WBS and communicate the status and progress towards completion of deliverables and milestones. The Project will be managed on the USG side by an interagency Project Coordination Team that will be part of the Operation Warp Speed program and will serve as a conduit for information between the company and all elements of the program to maximize the probability of success for this project. Sanofi Project Managers will work with the PCT to establish mechanisms and practices that ensure a level of communication that is commensurate with the urgent and highly accelerated pace that is demanded by the public health need for this vaccine. This will include maintaining detailed project plans/timelines that can be coordinated with Integrated Master Schedules maintained by OWS.

3.7.2 Technical Progress Reports

The Contractor will submit monthly technical progress reports on the 15th day of each month, to the Agreements Officer's Representative (AOR) describing activities performed during the previous calendar month. The appropriate formats for the Technical Progress Report and Executive Summary will be provided by the Government. The Technical Progress Reports will include project timelines and summaries of product manufacturing, testing, and clinical evaluation activities. A Technical Progress Report will not be required for the month in which the Final Report is due. The Contractor will be required to submit an electronic copy to the AOR. The Contractor should inform the AOR in advance if the delivery of a Technical Progress Report will be delayed.

3.7.3 Final Report

By the end date of the project period of performance, the SP will submit a draft comprehensive Final Report that details, documents, and summarizes the results of all work performed under the contract. A draft Final Report will be submitted to the US Government for review and comment, after which the Final Report will be submitted. SP will communicate the Final Report electronically as directed by the US Government Agreements Officer.

3.7.4 Meetings

SP will participate in regular meetings to coordinate and oversee the contract effort as directed by the US Government. Participants and frequency will be jointly agreed upon to ensure

efficient communication necessary to achieve optimal project progress and coordination with Operation Warp Speed.

The Agreements Officer's representative and the Contractor will hold monthly calls, or as directed by the Agreements Officer's representative. During this call the PI will discuss the activities performed and deliverables achieved during the reporting period, any problems that have arisen and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period will consist of each calendar month. SP may include other key personnel on the conference call to give detailed updates on specific projects and/or at the request of the Agreements Officer's representative.

(b) (4)

Monthly reports on project status shall be submitted no later than the 15th of the subsequent month for the prior reporting period. Monthly reporting will include a summary of work performed, work anticipated in the next reporting period, schedule and financial status (monthly forecast and incurred to date), variance explanations, and an updated risk matrix.

4.0 DELIVERABLES

Sanofi Pasteur shall provide all data deliverables in electronic format; file name format shall be: Project # - Deliverable Description. (ex. 19-13-001 Quarterly Technical and Business Status Report).

	Name	Finish	Milestone Reference	SOW	Govt Role	Data Rights
4.1	Mechanism of Action Study Report (Non-Clinical)	5/28/2021	5.1	3.3.1	Recipient	Unlimited Rights
4.2	Antibody Persistence Study Report (Non-Clinical)	1/15/2021	5.2	3.3.2	Recipient	Unlimited Rights
4.3	DART Report	4/9/2021	5.3	3.3.4	Recipient	Unlimited Rights
4.4	CoA Completed DS PIII	12/4/2020	5.4	3.2.1	Recipient	Unlimited Rights
4.5	Certificates of Compliance DP PIII	12/6/2020	5.5	3.2.9	Recipient	Unlimited Rights
4.6	(b) (4) PIII Supply & Regulatory Support	8/31/2022	5.6	3.4	Recipient	(b) (4)
4.7	Final Tech Transfer Comparability Report with Stability with Fujifilm Diosynth	2/22/2021	5.7	3.6	Recipient	Unlimited Rights
4.8	100 Million Doses DP Available	2/28/2021	5.8	3.6	Recipient	N/A
4.9	DS and DP Industrial-Scale Validation Report	6/30/2021	5.9	3.6	Recipient	Unlimited Rights
4.10	Temporary Storage of Final Drug Product 10-dose Vials (as FFP) (est. 6 months)	6/30/2021	5.10	3.6	Recipient	Unlimited Rights
4.11	Final CTD / BLA Document Submitted	9/29/2023	5.11	3.6.6	Recipient	Unlimited Rights
4.12	Clinical Trial Activities (VAT02)	8/28/2022	5.12	3.4.1	Recipient	Unlimited Rights

4.13	Clinical Trial Activities (VAT03)*	8/11/2023	5.13	3.4.2	Recipient	Unlimited Rights
4.14	Clinical Trial Activities (VAT04)	6/4/2022	5.14	3.4.2	Recipient	Unlimited Rights
4.15	Final PM Report	9/29/2023	5.15	3.7.3	Recipient	Unlimited Rights
4.16	Manufacturing Development Plan**	9/29/2023	N/A	3.7.1	Recipient	Unlimited Rights
4.17	FDA communications, meeting minutes, records	9/29/2023	N/A	3.1	Recipient	Unlimited Rights
4.18	FDA inspection and enforcement documents (e.g., notice of violations, 483s, foreign inspection reports, etc.)	9/29/2023	N/A	3.1	Recipient	Unlimited Rights
4.19	Confirmation of FDA Registration and Listing	9/29/2023	N/A	3.1	Recipient	Unlimited Rights
4.20	Lot Release and cGMP certification prior to shipment/Government acceptance.	9/29/2023	N/A	4.1	Recipient	Unlimited Rights
4.21	PL 115-92 Authorization Letter for DoD Medical Priorities	9/29/2023	N/A	7.4	Recipient	Unlimited Rights
4.22	Supply Chain Resiliency Plan or Sanofi Equivalent	Within 30 days after award		10.0 Appendix 1	Recipient	Limited Rights
4.23	Manufacturing Data Requirement or Sanofi Equivalent	Within 30 days after award		10.0 Appendix 1	Recipient	Limited Rights
4.24	Product Development Source Material & Manufacturing Reports and Projections	Within 30 days after award		10.0 Appendix 1	Recipient	Limited Rights
4.25	Work Location Report	Within 30 days after award		10.0 Appendix 1	Recipient	Limited Rights
4.26	Facility Security Plan or Sanofi Equivalent	Within 30 days after award		10.0 Appendix 1	Recipient	Limited Rights
4.27	Quarterly Technical and Business Status Report	Mar 31 st , Jun 30 th , Dec 31 st	5.17, 5.18, 5.19, 5.21, 5.22, 5.23, 5.25, 5.26, 5.27, 5.29, 5.30, 5.31		Recipient	GPR
4.28	Annual Technical and Business Status Report	Annually Sept 30th	5.16, 5.20, 5.24, 5.28, 5.32		Recipient	GPR
4.29	Monthly Status Report	Monthly	N/A		Recipient	GPR
	Period of Performance: 48 months					

**Although the cost quoted is for an efficacy study, the finish date is based on the immunogenicity trial described in the SoW and would change in the event an efficacy trial were required.*

*** The Manufacturing Development Plan will describe the manufacturing process for the drug/biologic product to ensure conformity with §501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21 United States Code (USC) §351 (a)(2)(B)), regarding good manufacturing practices (GMP). This plan shall describe, but is not limited to planned or completed drug substance studies; list of excipients and information to support the safety of excipients that, when appropriate, shall be cross-referenced; drug product and formulation development summary from initial concept through final design; physicochemical and biological properties; manufacturing process development and validation program documents; container closure system documents [description, choice, rationale]; microbiological attributes documents and plans; compatibility documents (e.g., precipitation); assay development and validation, stability plan; and any associated risks.*

4.1 Acceptance of Vaccine Doses

- BARDA's standard operating procedure (SOP) for product acceptance will be followed for any product accepted regardless of the method of delivery; stockpile (SNS), distribution location, held in vendor managed inventory (VMI), or others as defined at a future date.
 - Upon acceptance by the Agreements Officer Representative (AOR) of any lot of vaccine under this contract, title to such vaccine will transfer upon delivery of drug product to vendor-managed inventory and the Government's corresponding written acceptance of the delivery of each such lot of drug product. AOR will not withhold acceptance solely based on lack of product license or lack of approval for use under EUA.
 - Any deviations, out of specification (OOS) results, or other product issues shall be reported to the USG within 3 calendar days.
 - These materials should be maintained in the contractor's quality and inventory systems, ready for use in the continued manufacture of bulk material or final container doses intended for clinical use or use under Emergency Use Authorization or use under a BLA.
 - Notification must be made to the AOR or designated government representative for product acceptance at least 10 calendar days prior to delivery. Exceptions are permitted if approved by the AO.
 - The Government shall accept product that conforms to contract requirements based on Certificates of Analysis and Certificate(s) of Current Good Manufacturing Practices (cGMP) Conformity provided by Contractor.
 - Any product produced or stored under this contract is subject to inspection by a duly authorized US Government (USG) representative, and with reasonable notice (i.e., not less than 24 hours).
 - Upon receipt of Final Report and inspection (physical or representative, i.e., pictures), the AOR will review and recommend acceptance or rejection; the AOR will correspondingly notify the Contractor of acceptance or rejection. the USG reserves the right to audit, either by the USG and/or Government designee(s), the facilities used under this contract and all records related to the manufacture, testing, and storage of the product.
 - Upon delivery of product, notification of delivery quantities and any movement must be made to the AOR and government representatives (i.e., AOR and BARDA Regulatory and Quality Affairs Quality Branch).

- Unless otherwise mutually agreed upon by the parties, drug product shall be shipped, trackable by GPS, to the Government-designated sites within the continental United States.
- Contractor will retain physical risk of loss for all product stored as vendor-managed inventory until delivery and accepted by Government at government-designated site.
- Contractor will notify government (AO, AOR, and BARDA RQA Quality Branch) of any storage or quality deviation for product held in VMI, within 3 calendar days
- To the extent that Contractor is responsible for the correction, repair or replacement of Government property held in vendor-managed inventory and replacement upon loss or damage is feasible, the Government will accept replacement of such property.
- Vendor-managed storage of product manufactured under this agreement is supported through 30 June 2021, and, as such, the USG must either (a) take possession on or before this date and provide Contractor with disposition instructions in sufficient time to transfer physical material from Contractor by this date or (b) bilaterally modify this agreement to extend the period of vendor management of storage prior to this date.
- The USG understands that prices identified in this contract include insurance costs applicable to material that will become Government property, including product stored as vendor-managed inventory.
- USG right to inspect product: The AO and/or the AOR may perform inspection of materials and services. Inspections of material created under this contract may be made by a duly authorized USG representative, and with reasonable notice (i.e., not less than 24 hours). The USG reserves the right to conduct an audit, either by Government and/or Government designee(s), of the facilities used under this contract and all records related to the manufacture, testing, and storage of the product.
 - The manufacturer will make the necessary efforts to arrange and hold Final Drug Product (FDP) at a facility under their control. In this case, the manufacturer will:
 - Provide temperature-controlled storage at the manufacturer's site approved by the USG, according to cGMP and the Contractor's product specifications.
 - Store bulk lots and final containers physically segregated from other products
 - Ensure proper labeling of stored materials as USG property.
 - Execute stability testing of stored material in a manner consistent with the stability testing plan approved by the AOR. Report interim data and results to the AOR on a monthly basis.
 - Appropriately identify reserve samples that are representative of each lot of drug substance and drug product shall be retained. The reserve samples consist of at least twice the quantity necessary for all tests required to determine whether the drug substance and drug product meets its established specifications including a minimum of 60 months of stability testing.
 - Ensure stored materials are compliant with the Contractor's internal quality control system and are ready for use in further cGMP governed manufacturing of clinical material or licensed doses as directed by the USG.
 - Provide the government access to review the security systems in place and request updates as needed.
 - Include in monthly report inventory for drug substance and/or drug product (lot number, number of lots, number of vials), including inventory quantity changes, current quantity, storage facility/location, manufacturing date, latest

- stability result for potency, date of next expected stability result and the current expiration date (if applicable).
 - Ensure that material being relocated for the contractors' convenience is adequately insured at no cost to the government and with AOR approval.
 - Conduct testing necessary to ensure continued use of the stored material for pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed doses.
 - Make appropriate updates to the regulatory documentation supporting the continued use of the stored material for pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed doses.
 - If using a subcontracted storage site, provide the quality agreement, specify the location and terms of the storage contract and receive approval by the AOR.
- The contractor may request to arrange and hold FDP at a USG contracted facility (e.g., SNS facility). In this case the provisions immediately above still apply with the addition that the manufacturer enter into a quality agreement with the USG contracted facility. All costs to move FDP to the USG contracted facility remain with the manufacturer. Title remains with the manufacturer.
- The manufacturer may invoice for costs incurred while in VMI and prior to delivery and acceptance of services and/or product. Product in VMI that falls into any of the following categories shall be replaced by the contractor at no cost to the USG:
 - If product does not meet any criterion outlined in this contract.
 - If product is deemed to be recalled for any reason, as outlined in the Product Recalls, Including Removal and corrections published by U.S. Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs; or based upon Chapter 7 of the Regulatory Procedures Manual of March 2007.
- The contractor may invoice upon USG delivery and acceptance of services and/or product. In this case, the terms outlined in Responsibility for Supplies below apply.
- The Contractor cannot reclaim title to product upon acceptance by the USG. Prior to expiration or termination of this contract, the USG may affect final distribution of any vaccines remaining in storage by any one or combination of the following methods:
 - The USG may elect to require shipment of the vaccine to USG facilities or to state and local health agencies and/or other providers.
 - The USG may direct the Contractor to destroy all quantities remaining in storage. In this case, a letter of disposition will be provided to the USG.

If, for whatever reason, the USG takes possession while in VMI, these instructions will be defined as FOB-origin. Any vaccine lot under this contract, title to such vaccine will transfer upon delivery of drug product to VMI and the Government's corresponding written acceptance of the delivery of each such lot of drug product. These materials should be maintained in the contractor's quality and inventory systems, ready for use in the continued manufacture of bulk material or final container doses intended for clinical use or use under Emergency Use Authorization or use under a BLA as outlined above. The elements outlined above remain in effect. The difference being that the USG bears responsibility and associated costs with

transportation to final destination and cost to replace product for losses en route to final destination.

Responsibility for Supplies

(a) Title to supplies furnished under this contract shall pass to the Government upon formal acceptance, regardless of when or where the Government takes physical possession, unless the contract specifically provides for earlier passage of title.

(b) Unless the contract specifically provides otherwise, risk of loss of or damage to supplies shall remain with the Contractor until, and shall pass to the Government upon --

(1) Delivery of the supplies to a carrier, if transportation is f.o.b. origin; or

(2) Acceptance by the Government or delivery of the supplies to the Government at the destination specified in the contract, whichever is later, if transportation is f.o.b. destination.

(c) Paragraph (b) of this section shall not apply to supplies that so fail to conform to contract requirements as to give a right of rejection. The risk of loss of or damage to such nonconforming supplies remains with the Contractor until cure or acceptance. After cure or acceptance, paragraph (b) of this section shall apply.

The contractor shall provide all data deliverables in electronic format, file name format shall be: Project # - Deliverable Description. (example. 2011-005 Quarterly Technical and Business Status Report).

The USG will provide acceptance of all data deliverables within sixty (30) days of receipt of the final version. Drafts will be reviewed and comments provided to the contractor within 30 days.

5.0 MILESTONE PAYMENT SCHEDULE

Milestone Reference	Name	Deliverable Reference	Finish	Total Cost
5.1	Mechanism of Action Study Report (Non-Clinical)	4.1	5/28/2021	(b) (4)
5.2	Antibody Persistence Study Report (Non- Clinical)	4.2	1/15/2021	
5.3	DART Report	4.3	4/9/2021	
5.4	CoA Completed DS PIII	4.4	12/4/2020	
5.5	Certificates of Compliance DP PIII	4.5	12/6/2020	
5.6	(b) (4) PIII Supply & Regulatory Support	4.6	8/31/2022	
5.7	Final Tech Transfer Comparability Report with Stability with Fujifilm Diosynth	4.7	2/22/2021	
5.8	100M Doses DP Available (as FFP – Firm Fixed Price)	4.8	2/28/2021	

5.9	DS and DP Industrial-Scale Validation Report	4.9	6/30/2021	(b) (4)
5.10	Temporary Storage of Final Drug Product 10-dose Vials (as FFP) (est. 6 months)*	4.10	6/30/2021	
5.11	Final CTD / BLA Document Submitted		9/29/2023	
5.12	Clinical Trial Activities (VAT02)	4.11	8/28/2022	
5.13	Clinical Trial Activities (VAT03)**	4.12	8/11/2023	
5.14	Clinical Trial Activities (VAT04)	4.13	6/4/2022	
5.15	Final PM Report	4.14	9/29/2023	
5.16	Annual Technical and Business Status Report	4.28	9/30/2020	\$0
5.17	Quarterly Technical and Business Status Report	4.27	12/31/2020	\$0
5.18	Quarterly Technical and Business Status Report	4.27	3/31/2021	\$0
5.19	Quarterly Technical and Business Status Report	4.27	6/30/2021	\$0
5.20	Annual Technical and Business Status Report	4.28	9/30/2021	\$0
5.21	Quarterly Technical and Business Status Report	4.27	12/31/2021	\$0
5.22	Quarterly Technical and Business Status Report	4.27	3/31/2022	\$0
5.23	Quarterly Technical and Business Status Report	4.27	6/30/2022	\$0
5.24	Annual Technical and Business Status Report	4.28	9/30/2022	\$0
5.25	Quarterly Technical and Business Status Report	4.27	12/31/2022	\$0
5.26	Quarterly Technical and Business Status Report	4.27	3/31/2023	\$0
5.27	Quarterly Technical and Business Status Report	4.27	6/30/2023	\$0
5.28	Annual Technical and Business Status Report	4.28	9/30/2023	\$0
5.29	Quarterly Technical and Business Status Report	4.27	12/31/2023	\$0
5.30	Quarterly Technical and Business Status Report	4.27	3/31/2024	\$0
5.31	Quarterly Technical and Business Status Report	4.27	6/30/2024	\$0
5.32	Final Technical and Business Status Report	4.28	9/30/2024	(b) (4)
Period of Performance – 48 months			Cost, No Fee	Total: \$1,769,013,470

* Insurance costs to be determined.

**Although the cost quoted is for an efficacy study, the finish date is based on the immunogenicity trial described in the SoW and would change in the event an efficacy trial were required.

5.1 Most Favored Nation Clause

(i) Due to the exceptional and unprecedented nature of the COVID-19 threat to global public health and in recognition of the long historical partnership between the U.S. Government and Sanofi Pasteur working on global pandemic solutions, as well as the investments made towards the development of a safe and effective vaccine against COVID-19, Sanofi Pasteur agrees that it will not sell any COVID-19 vaccine licensed under this Agreement to any nation that is a member of the Group of Seven plus Switzerland (“Covered Nation”) at a price that is more favorable than those set forth in this Project Agreement.

(ii) If, at any time prior to December 31, 2021, Sanofi Pasteur enters into any agreement with a Covered Nation to sell COVID-19 vaccine doses at a price lower than the price currently paid by the U.S. Government for the same COVID-19 vaccine doses, Sanofi Pasteur shall provide notice within 30 days to the U.S. Government and the U.S. Government may elect, at its discretion, to receive the benefit of this provision and receive COVID-19 vaccine doses at that lower price.

(iii) Upon any such election by the U.S. Government, this Project Agreement shall be deemed to have been amended and modified such that, from the date on which the more favorable pricing was first provided to any Covered Nation (the “Amended Pricing Effective Date”), the U.S. Government will receive that lower price for all orders of COVID-19 vaccine doses following that Amended Pricing Effective Date.

(iv) Additionally, Sanofi Pasteur will provide a credit, expressed as a cost share, towards future U.S. Government payments made under this Project Agreement in the amount that the U.S. Government paid above the more favorable pricing for any purchases of COVID-19 vaccine doses placed prior to the Amended Pricing Effective Date. In the event the credit exceeds the remaining payments due Sanofi Pasteur under this Project Agreement, the parties agree to negotiate how best to protect the Government’s interest as part of the Close-out Procedures specified in Section 2.05 of Other Transaction Agreement number W15QKN-16-9-1002.

(v) Any price reductions provided hereunder are not intended as an inducement or reward for any procurement or purchasing decisions by the U.S. Government of any Sanofi Pasteur product.

6.0 SHIPPING PROVISIONS

The contractor shall submit Quarterly, Annual, and final reports in accordance with the Base Agreement to deliverables.mcdc@ati.org. All deliverables intended for the AOR shall be delivered electronically to the AOR identified below.

A copy of all data deliverables shall be sent to usarmy.detrick.dod-jpeo-cbrnd.mbx.otadeliverable@mail.mil.

Shipping information shall be provided upon acceptance of the manufactured product.

7.0 INTELLECTUAL PROPERTY and REGULATORY RIGHTS

7.1 Patent Rights

Patent rights and rights in any Subject Invention, as that term is defined in Article X Sections 10.01-10.13 of Other Transaction Agreement number W15QKN-16-9-1002, shall be governed by Article X of the OTA and consistent with W15QKN-16-9-1002. These patent rights and rights in any Subject Invention include, but are not limited to, the Government's retention of certain licensure rights in subject inventions and applicability of the Government's March-In rights. Specifically, with respect to any Subject Invention in which Sanofi retains title and as set forth in Article X Section 10.02, the Government shall have a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world. Furthermore, Sanofi agrees that, with respect to any Subject Invention in which it has retained title, the Government, has the right to require Sanofi to obtain and grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances as set forth in Article X, Section 10.10.

7.2 Technical Data Rights

Sanofi Pasteur grants the Government Unlimited Rights, as that term is defined DFARS 227.2013, in all Sanofi Pasteur data (excluding with respect to (b) (4) data) that is delivered to the Government under this Project Agreement.

7.3 Confidential Information

7.3.1 General

Neither Party, as the Receiving Party, shall, directly or indirectly, divulge or reveal to any person or entity any confidential information of the other Party without the Disclosing Party's prior written consent, or use such Confidential Information except as permitted under this Project Agreement.

7.3.2 Exclusion

Such obligation of confidentiality shall not apply to information which the Receiving Party can demonstrate through competent evidence: (i) was at the time of disclosure in the public domain; (ii) has come into the public domain after disclosure through no breach of this contract; (iii) was known to the Receiving Party prior to disclosure thereof by the Disclosing Party; (iv) was lawfully disclosed to the Receiving Party by a Third Party which was not under an obligation of confidence to the Disclosing Party with respect thereto; or (v) was approved for public release by prior written permission of the Disclosing Party.

7.4 Regulatory Rights

This Project Agreement involves research with an investigational drug, biologic or medical device that is regulated by the U.S. Food and Drug Administration (FDA) and requires FDA pre-market approval or clearance before commercial authorization. It is expected that this contract will result in the FDA authorization, clearance, and commercialization of Sanofi's Adjuvanted Recombinant COVID-19 Vaccine as a Vaccine for SARS-CoV-2 Coronavirus (the "Technology"). The Contractor is the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), emergency use

authorization (EUA), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) that controls research under this contract. As the Sponsor of the Regulatory Application to FDA (as the terms “sponsor” and “applicant” are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), the Contractor has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

The Parties agree that Contractor has invested significant time and resources in its platform and IP and is the best company situated to manage production of the Adjuvanted Recombinant COVID-19 Vaccine. At the same time, the Parties acknowledge that the Government has made significant investments in the prototype. Accordingly, the Contractor and the Government agree to the following:

- a. Communications. Contractor will provide the Government with all communications and summaries thereof, both formal and informal, to or from FDA regarding the Technology and ensure that the Government representatives are invited to participate in any formal or informal Sponsor meetings with FDA;
- b. 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. The Awardee recognizes that only the DoD can utilize PL 115-92. As such, the Awardee will work proactively with the Government to leverage this law to its maximum potential under this Project Agreement. The Awardee shall submit Public Law 115-92 Sponsor Authorization Letter that will be delivered to the designated OWS POC(s) within 30 days of award.
- c. Rights of Reference. To the extent necessary or useful to exercise the Government's rights under the license grants in Section 7 of this Project Agreement and subject to the restrictions set forth in that section, Sanofi Pasteur hereby grants to the Government and its permitted sublicensees a limited "right of reference or use" (as that term is defined in 21 C.F.R. § 314.3(b), as amended from time to time) strictly for COVID-19 or other Material Threat (as defined at Section 319 of the Public Health Service Act) Purposes to Sanofi Pasteur's filings to the FDA in connection with the Regulatory Application (excluding such right of reference or use for (b) (4) and Sanofi Pasteur shall provide appropriate notification of the Government's access and reference rights to the applicable regulatory authorities requested by the Government for the limited purposes described above. Sanofi Pasteur agrees to provide a letter of cross-reference to the Government and file such letter with the appropriate FDA office. This provision is in addition to any rights in technical data described earlier in this document, excluding with respect to (b) (4)

8.0 ENSURING SUFFICIENT SUPPLY OF THE PRODUCT

1. In recognition of the Government's significant funding for the development and manufacturing of the product in this Project Agreement and the Government's need to provide sufficient quantities of a COVID-19 vaccine to protect the United States population, the

Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions are met:

- a. Sanofi gives written notice, required to be submitted to the Government no later than 15 business days, of:
 - i. any formal management decision to terminate manufacturing of this product vaccine prior to delivery of 100 million doses to USG, or;
 - ii. any formal management decision to discontinue sale of this product vaccine to the Government prior to delivery of 100 million doses to USG; or
 - iii. any filing that anticipates Federal bankruptcy protection; and
- b. Sanofi has submitted an Emergency Use Authorization under §564 of the FD&C Act or a biologics license application provisions of §351(a) of the Public Health Service Act (PHSA).

2. If both conditions listed in section (a) occur, Sanofi, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of this product vaccine with a third party for exclusive sale to the U.S. Government:

- a. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Sanofi Background Patent, Copyright, other Sanofi Intellectual Property, Sanofi Know-How, Sanofi Technical Data rights necessary to manufacture or have manufactured the vaccine;
- b. necessary FDA regulatory filings or authorizations owned or controlled by Sanofi related to this product vaccine and any confirmatory instrument pertaining thereto (excluding with respect to (b) (4)); and
- c. any outstanding Deliverables contemplated or materials purchased under this Project Agreement.

3. This Article shall be incorporated into any contract for follow-on activities for the Government to acquire and use additional doses of the product. Per section 1.3, the estimated quantity for follow-on production/procurement is sufficient quantities to vaccinate approximately 300 million people.

4. This Article will survive the acquisition or merger of the Contractor by or with a third party. This Article will survive the expiration of this agreement.

9.0 PUBLICATION POLICY

9.1 Publication of Clinical Data Related to the Trial

Any publication or presentation related to the clinical trial must be submitted to SP (b) (4) for review before submission of the manuscript. After publication of the results of the trial, any participating center may publish or otherwise use its own data provided that any publication of data from the trial gives recognition to the trial group. In addition, SP (b) (4) shall be offered an association with all such publications, it being understood that SP (b) (4) are each entitled to refuse the association.

SP (b) (4) must have the opportunity to review all proposed abstracts, manuscripts, or presentations regarding these trials at least 30 days prior to submission for publication / presentation. Any information identified by SP (b) (4) as confidential must be deleted prior to submission, it being understood that the results of this trial are not to be considered confidential, provided that any publication of data from the trial gives recognition to the trial group. In addition, SP (b) (4) shall be offered an association with all such publications, it being understood that SP (b) (4) are each entitled to refuse the association.

9.2 Publication of nonclinical Subject Data

Publication of any nonclinical Subject Data shall be prohibited without the express permission of Sanofi Pasteur (b) (4).

10.0 SECURITY

The security classification level for this effort is **UNCLASSIFIED**

The Attached Appendix 1 is hereby incorporated in this SOW.

11.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)

11.1 Associate Contractor Agreement (ACA)

In the following clause "Contractor" shall mean "subcontractor/supplier" and

a) It is recognized that success of the Adjuvanted Recombinant COVID-19 Vaccine Development research effort depends in part upon the open exchange of information between the various Associate Contractors involved in the effort. This clause is intended to insure that there will be appropriate coordination and integration of work by the Associate Contractors to achieve complete compatibility and to prevent unnecessary duplication of effort.

By executing this contract, the Contractor assumes the responsibilities of an Associate Contractor. For the purpose of this clause, the term Contractor includes subsidiaries, affiliates, and organizations under the control of the contractor (e.g. subcontractors).

(b) Work under this contract may involve access to proprietary or confidential data from an Associate Contractor. To the extent that such data is received by the Contractor from any Associate Contractor for the performance of this contract, the Contractor hereby agrees that any proprietary information received shall remain the property of the Associate Contractor and shall be used solely for the purpose of the Adjuvanted Recombinant COVID-19 Vaccine Development research effort. Only that information which is received from another contractor in writing and which is clearly identified as proprietary or confidential shall be protected in accordance with this provision. The obligation to retain such information in confidence will be satisfied if the Contractor receiving such information utilizes the same controls as it employs to avoid disclosure, publication, or dissemination of its own proprietary information. The receiving Contractor agrees to hold such information in confidence as provided herein so long as such information is of a proprietary/confidential or limited rights nature.

(c) The Contractor hereby agrees to closely cooperate as an Associate Contractor with the other Associate Contractors on this research effort. This involves as a minimum:

- (1) Maintenance of a close liaison and working relationship;
 - (2) Maintenance of a free and open information network with all Government-identified Associate Contractors;
 - (3) Delineation of detailed interface responsibilities;
 - (4) Entering into a written agreement with the other Associate Contractors setting forth the substance and procedures relating to the foregoing, and promptly providing the Agreements Officer/Procuring Contracting Officer with a copy of same; and,
 - (5) Receipt of proprietary information from the Associate Contractor and transmittal of Contractor proprietary information to the Associate Contractors subject to any applicable proprietary information exchange agreements between associate contractors when, in either case, those actions are necessary for the performance of either.
- (d) In the event that the Contractor and the Associate Contractor are unable to agree upon any such interface matter of substance, or if the technical data identified is not provided as scheduled, Sanofi Pasteur shall promptly notify the Agreements Officer Representative and OTA Program Manager. The Government will determine the appropriate corrective action and will issue guidance to the affected Contractor.
- (e) The Contractor agrees to insert in all subcontracts hereunder which require access to proprietary information belonging to the Associate Contractor, a provision which shall conform substantially to the language of this clause, including this paragraph (e).

11.2 (a) The Contractor should enter into Associate Contractor Agreements (ACA) for any portion of the contract requiring joint participation in the accomplishment of the Government's requirement. The agreements should include the basis for sharing information, data, technical knowledge, expertise, and/or resources essential to the integration of the Adjuvanted Recombinant COVID-19 Vaccine Development, to ensure the greatest degree of cooperation for the development of the program to meet the terms of the contract. Associate contractors are listed in (g) below.

(b) ACAs should include the following general information:

- (1) Identify the associate contractors and their relationships.
- (2) Identify the program involved and the relevant Government contracts of the associate contractors.
- (3) Describe the associate contractor interfaces by general subject matter.
- (4) Specify the categories of information to be exchanged or support to be provided.

(5) Include the expiration date (or event) of the ACA.

(6) Identify potential conflicts between relevant Government contracts and the ACA; include agreements on protection of proprietary data and restrictions on employees.

(c) Provide a copy of such agreement to the Contracting Officer for review before execution of the document by the cooperating contractors.

(d) The Contractor is not relieved of any contract requirements or entitled to any adjustments to the contract terms because of a failure to resolve a disagreement with an associate contractor.

(e) Liability for the improper disclosure of any proprietary data contained in or referenced by any agreement rests with the parties to the agreement, and not the Government.

(f) All costs associated with the agreements are included in the negotiated cost of this contract. Agreements may be amended as required by the Government during the performance of this contract.

(g) The following contractors are associate contractors with whom agreements are required:

Contractor	Address	Program / Contract
Sanofi Pasteur	(b) (4)	OWS Project Entitled: Adjuvanted Recombinant COVID-19 Vaccine Development
(b) (4)	(b) (4)	(b) (4)

12.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

(b) (4) on behalf of the Government, shall provide as GFM, 100M doses of Adjuvant

(b) (4)

13.0 AGREEMENTS OFFICER'S REPRESENTATIVE (AOR) AND ALTERNATE AOR CONTACT INFORMATION

AOR

NAME: (b) (6)

EMAIL: (b) (6)

PHONE: (b) (6)

AGENCY NAME/DIVISION/SECTION: Department of Health and Human Services,
Biomedical Advanced Research and Development Agency

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	• 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	• 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	• 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	• identification and marking of sensitive information • access control • storage of information • document control procedures • retention/ destruction requirements

Information Technology/Cyber Security Policies and Procedures	• 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 • system document control • system backup • system disaster recovery • incident response • system audit procedures • property accountability
2. Site Security Master Plan 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.	
3. Site Threat / Vulnerability / Risk Assessment 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.	
4. Physical Security Description:	
Closed Circuit Television (CCTV) Monitoring	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	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	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	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. 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	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	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	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	a) Conduct new employee security awareness training. b) Conduct and maintain records of annual security awareness training.
Security Management	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	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	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	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	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	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	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. • 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.	

UNDEFINITIZED PROJECT ACTION

MCDC2011-005 is a hybrid Cost/Fixed Price Agreement that will be awarded under W15QKN-16-9-1002 (hereinafter "Agreement"). Due to urgency concerns, this Undefinitized Project Action (UPA) is being issued to Sanofi Pasteur, Inc. (hereinafter "Contractor") for Adjuvanted Recombinant COVID-19 Vaccine Development. The following is hereby incorporated as part of this Agreement.

1. DEFINITIZATION:

- a) This Agreement covers a hybrid Cost/Fixed Price UPA that awards prototype project MCDC2011-005. The Contractor agrees to promptly begin negotiating with the Agreements Officer on the terms of a definitive Agreement for the project, which will include: (1) all mutually agreeable terms and conditions related to this Agreement, and (2) all other terms and conditions required by law. The Contractor will be required to submit a qualifying cost proposal with all necessary supporting documentation, in order to allow for a full evaluation of costs.
- b) The schedule for definitizing this Agreement is as follows:
 - i. Receipt of Qualifying Proposal: 10 September 2020
 - ii. Estimated Start of Negotiations: 01 October 2020
 - iii. Estimated Date of Definitization: 09 December 2020
- c) If a definitive Agreement is not finalized to supersede this UPA by the target date in paragraph 2(b)(iii), or within any extension granted in writing by the Agreements Officer, the Agreements Officer may, with the approval of the Army Contracting Command-New Jersey, Senior Contracting Official, unilaterally determine a fair and reasonable price. This determination is subject to Contractor appeal, as provided for in the Disputes article of W15QKN-16-9-1002, but the Contractor shall not cease performance of this Agreement while proceeding through the dispute process.
- d) After the Agreements Officer's determination of a fair and reasonable price, the Agreement shall be governed by all of the terms and conditions of the definitive Agreement. Furthermore, all the terms and conditions of this UPA shall continue in effect, except for those that by their nature apply only to UPAs.
- e) The Government and Contractor agree that this UPA will include a ceiling in the amount of \$1,769,013,470. This ceiling may be adjusted only by the written agreement of both parties.

2. PAYMENT OF ALLOWABLE COSTS BEFORE DEFINITIZATION:

Prior to definitization of this Agreement, the Government will reimburse the Contractor for all allowable and allocable costs up to 50% of the approved Not-To-Exceed (NTE) Price of \$1,769,013,470. At any time before a payment, the Agreements Officer may have the Contractor's invoices or vouchers audited. Any payment may be (1) reduced by any amounts found by the Agreements Officer not deemed authorized in accordance with the Statement of Work, or (2) adjusted for overpayments made on preceding invoices or vouchers.

3. LIMITATIONS ON OBLIGATIONS:

The Government will not obligate more than 50 percent of the NTE Price before definitization.

4. LIMITATION OF GOVERNMENT LIABILITY:

- a) In performance of this Agreement, the Contractor is not authorized to make expenditures or incur obligations exceeding \$1,769,013,470 dollars.
- b) The maximum amount for which the Government shall be liable if this Agreement is terminated is \$1,769,013,470 dollars.

5. EXECUTION AND COMMENCEMENT OF WORK:

Upon acceptance by both parties, the Contractor shall proceed with performance of the Statement of Work, including the purchase of any necessary materials.

Form Approved
OMB No. 0704-0188

A. CONTRACT LINE ITEM NO.	B. EXHIBIT A	C. CATEGORY: TDP _____ TM _____ OTHER <u>General/Admin Data</u>
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1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
A001	Quality Assessment Report	Quality Report

7. DD 250 REQ No	9. DIST STATEMENT REQUIRED A	10. FREQUENCY Once	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION	
8. APP CODE NA		11. AS OF DATE NA	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	Dr

4. The Data Item Description (DID) may be obtained from <http://quicksearch.dla.mil/>.

9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24.

12. & 13. The contractor shall submit the Quality Report within 30 days of award for Government review.

14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: (b) (6)

*, and the Contracting Officer** (KO), (b) (6)

BARDA*	1	1	0
ACC -New Jersey**	0	1	0
15. TOTAL 	1	2	0

4. AUTHORITY (Data Acquisition Document No.) DI-ADMN-81250 (Tailored)	5. CONTRACT REFERENCE C.4.b	6. REQUIRING OFFICE BARDA
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7. DD 250 REQ No	9. DIST STATEMENT REQUIRED A	10. FR QUENCY Monthly	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION		
8. APP CODE NA		11. AS OF DATE NA	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES	
						Draft
					Reg	Repro

4. The Data Item Description (DID) may be obtained from <http://quicksearch.dla.mil/>.
9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24.
12. & 13. 1). The contractor shall provide agendas and read-ahead material as required one day prior to the meetings and shall provide minutes of each meeting to the Government. 2). The contractor shall include key subcontractors as attendees at these teleconferences when applicable. 3). The contractor shall provide meeting minutes within three (3) business days after each formal scheduled meeting/teleconference conducted with the Government.
14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative; (b) (6)
*, and the Contracting Officer** (KO), (b) (6)

BARDA*	0	1	0
ACC -New Jersey**	0	1	0
15. TOTAL		2	0

G. PREPARED BY Exemption (b)(6) AMERICAN	H. DATE Exemption (b)(4)	I. APPROVED BY Exemption (b)(6) Exemption (b)(6)	J. DATE Exemption (b)(4)
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CONTRACT DATA REQUIREMENTS LIST (2 Data Items)										Form Approved OMB No. 0704-0188					
The public reporting burden for this collection of information is estimated to average 220 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.															
A. CONTRACT LINE ITEM NO.			B. EXHIBIT A		C. CATEGORY: TDP _____ TM _____ OTHER <u>General/Admin Data</u>										
D. SYSTEM/ITEM Production of AS03 Adjuvant to support Exemption (b)(4) doses				E. CONTRACT/PR NO.			F. CONTRACTOR GlaxoSmithKline, LLC								
1. DATA ITEM NO. A003		2. TITLE OF DATA ITEM Conference Minutes				3. SUBTITLE Ad Hoc Meetings									
4. AUTHORITY (Data Acquisition Document No.) DI-ADMN-81250 (Tailored)				5. CONTRACT REFERENCE C.4.c			6. REQUIRING OFFICE BARDA								
7. DD 250 REQ No		9. DIST STATEMENT REQUIRED A		10. FREQUENCY As Required		12. DATE OF FIRST SUBMISSION Refer to Block 16		14. DISTRIBUTION							
8. APP CODE NA				11. AS OF DATE NA		13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16		a. ADDRESSEE		b. COPIES					
										Draft		Final			
										Reg		Repro			
16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . 9. Distribution Statement A: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. & 13. In addition to the monthly meetings, additional ad hoc meetings to address specific issues or to convey time-sensitive updates or scientific data related to the program will be held.. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: (b) (6) *, and the Contracting Officer** (KO), (b) (6))								BARDA*		0		1		0	
								ACC -New Jersey**		0		1		0	
								15. TOTAL		0		2		0	
1. DATA ITEM NO. A004		2. TITLE OF DATA ITEM Incident Report				3. SUBTITLE Incident Report									
4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-82071 (Tailored)				5. CONTRACT REFERENCE C.4.d			6. REQUIRING OFFICE BARDA								
7. DD 250 REQ No		9. DIST STATEMENT REQUIRED A		10. FREQUENCY As Required		12. DATE OF FIRST SUBMISSION Refer to Block 16		14. DISTRIBUTION							
8. APP CODE NA				11. AS OF DATE NA		13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16		a. ADDRESSEE		b. COPIES					
										Draft		Final			
										Reg		Repro			
16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . 9. Distribution Statement A: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. & 13. A written summary report shall be submitted within three (3) business days of an incident, to include what happened, what was the impact, if there are any available corrective actions and a time line for when the corrective actions would be in place. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: (b) (6) *, and the Contracting Officer** (KO), (b) (6))								BARDA*		0		1		0	
								ACC -New Jersey**		0		1		0	
								15. TOTAL		0		2		0	
G. PREPARED BY Exemption (b)(6)				H. DATE Exemption (b)(4)		I. APPROVED BY Exemption (b)(6)				J. DATE Exemption (b)(4)					

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST
(2 Data Items)Form Approved
OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 220 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.

A. CONTRACT LINE ITEM NO.
B. EXHIBIT
A
C. CATEGORY:
TDP _____ TM _____ OTHER General/Admin Data**D. SYSTEM/ITEM**
Production of AS03 Adjuvant to support **Exemption (b)(4)** doses
E. CONTRACT/PR NO.
F. CONTRACTOR
GlaxoSmithKline, LLC**1. DATA ITEM NO.**
A005
2. TITLE OF DATA ITEM
Contract Summary Report
3. SUBTITLE
Draft and Final Reports**4. AUTHORITY (Data Acquisition Document No.)**
DI-ADMN-80447A
5. CONTRACT REFERENCE
C.4.e
6. REQUIRING OFFICE
BARDA**7. DD 250 REQ**
No
9. DIST STATEMENT REQUIRED
C
10. FREQUENCY
Twice
12. DATE OF FIRST SUBMISSION
Refer to Block 16
11. AS OF DATE
NA
13. DATE OF SUBSEQUENT SUBMISSION
Refer to Block 16
14. DISTRIBUTION
a. ADDRESSEE
b. COPIES
Draft Final
Reg Repro**16. REMARKS**
4 The Data Item Description (DID) may be obtained from <http://quicksearch.dla.mil/>
9 Distribution Statement A: Distribution authorized to U S Government agencies and their Contractors (Administrative or Operational Use) Determination made July 18, 2020 Distribution guidance is included in DoD Instruction 5230 24
12 & 13 Due 30 calendar days before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP The Progress Report shall contain manufacturing process description including:
• batch number
• date and location of manufacture (including building, room, line number)
• shelf life
• description of process/testing
• final production volume
• complete list of analytical tests performed and results
• Certificate(s) of Analysis
• Certificate(s) of Current Good Manufacturing Practices (cGMP) Conformity
• Any deviations
• Final status, e.g., released, etc
• Storage bag, vial, and container closure details
14 Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: **(b) (6)***, and the Contracting Officer** (KO), Trisha
15. TOTAL → 1 2 0**1. DATA ITEM NO.**
2. TITLE OF DATA ITEM
3. SUBTITLE**4. AUTHORITY (Data Acquisition Document No.)**
5. CONTRACT REFERENCE
6. REQUIRING OFFICE**7. DD 250 REQ**
9. DIST STATEMENT REQUIRED
10. FREQUENCY
12. DATE OF FIRST SUBMISSION
11. AS OF DATE
13. DATE OF SUBSEQUENT SUBMISSION
14. DISTRIBUTION
a. ADDRESSEE
b. COPIES
Draft Final
Reg Repro**16. REMARKS**
NOT USED
15. TOTAL ▶**G. PREPARED BY**
Exemption (b)(6)
H. DATE
Exemption (b)(4)
I. APPROVED BY
Exemption (b)(6)
J. DATE
Exemption (b)(4)

17. PRICE GROUP

18. ESTIMATED
TOTAL PRICE

17. PRICE GROUP

18. ESTIMATED
TOTAL PRICE

MULTI-HHS-NIAID-20-2551, 20-2560, 20-2568-A-000118

CONTRACT DATA REQUIREMENTS LIST (2 Data Items)						Form Approved OMB No. 0704-0188		
The public reporting burden for this collection of information is estimated to average 220 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.								
A. CONTRACT LINE ITEM NO.		B. EXHIBIT A		C. CATEGORY: TDP _____ TM _____ OTHER _____				
D. SYSTEM/ITEM Production of AS03 Adjuvant to support Exemption (b)(4) doses		E. CONTRACT/PR NO.		F. CONTRACTOR GlaxoSmithKline, LLC				
1. DATA ITEM NO. A006	2. TITLE OF DATA ITEM Internal Contractor Technical Data			3. SUBTITLE Product Development Source Material and Manufacturing Reports and Projections				
4. AUTHORITY (Data Acquisition Document No.) DI-SESS-81309		5. CONTRACT REFERENCE		6. REQUIRING OFFICE BARDA				
7. DD 250 REQ No	9. DIST STATEMENT REQUIRED C	10. FREQUENCY Monthly	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION				
8. APP CODE A		11. AS OF DATE NA	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE		b. COPIES		
						Draft	Final	
						Reg	Repro	
16. REMARKS 4 The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ 9 Distribution Statement C: Distribution authorized to U S Government agencies and their Contractors (Administrative or Operational Use) Determination made July 18, 2020 Distribution guidance is included in DoD Instruction 5230 24 12 & 13 1) The 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 2) The contractor will update the Dose Tracking Template weekly during manufacturing campaigns and daily during response operations (where a Public Health Emergency has been declared) and COVID-19 response, with the first deliverable submission within 15 days of award/modification Updates to be provided weekly in advance of commercial-scale manufacturing and daily once material for use in response operations begins manufacture 3) 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 BARDA in writing The Product Development and Source Material report to be submitted via spreadsheet; Dose Tracking can be completed via spreadsheet or other format (e g XML or JSON) as agreed to by USG and company 14 Submit as an electronic file in Microsoft Office (i e Word, Excel, Power Point) via email to the BARDA representative: (b) (6) *, and the Contracting Officer** (KO), (b) (6)				BARDA*		0	1	0
				ACC -New Jersey**		0	1	0
				15. TOTAL				0
1. DATA ITEM NO. A007	2. TITLE OF DATA ITEM Contract Summary Report			3. SUBTITLE Contractor Location				
4. AUTHORITY (Data Acquisition Document No.) DI-ADMN-80447A		5. CONTRACT REFERENCE		6. REQUIRING OFFICE BARDA				
7. DD 250 REQ NO	9. DIST STATEMENT REQUIRED C	10. FREQUENCY Once	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION				
8. APP CODE NA		11. AS OF DATE NA	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE		b. COPIES		
						Draft	Final	
						Reg	Repro	
16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. & 13. The contractor will submit Work Locations Report within 5 business days of contract award, within 30 business days after a substantive location or capabilities change, and 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. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: (b) (6) *, and the Contracting Officer** (KO), (b) (6)				BARDA*		0	1	0
				ACC -New Jersey**		0	1	0
				15. TOTAL				0
G. PREPARED BY Exemption (b)(6)		H. DATE Exemption (b)(4)		I. APPROVED BY Exemption (b)(6)		J. DATE Exemption (b)(4)		

17. PRICE GROUP

18. ESTIMATED
TOTAL PRICE

17. PRICE GROUP

18. ESTIMATED
TOTAL PRICE

MULTI-HHS-NIAID-20-2551, 20-2560, 20-2568-A-000119

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEM Offeror To Complete Block 12, 17, 23, 24, & 30				1. Requisition Number SEE SCHEDULE		Page 1 Of 32	
2. Contract No. W15QKN-20-C-0048		3. Award/Effective Date 2020JUL30		4. Order Number		5. Solicitation Number	
7. For Solicitation Information Call:		A. Name (b) (6)		B. Telephone Number (No Collect Calls) (b) (6)		6. Solicitation Issue Date	
9. Issued By ARMY CONTRACTING COMMAND - NJ PICATINNY ARSENAL, NJ 07806-5000 Code W15QKN Email: (b) (6)				10. This Acquisition is ☐ Unrestricted ☐ OR ☐ Set Aside: % For: ☐ Small Business ☐ Women-Owned Small Business (WOSB) Eligible Under the Women-Owned Small Business Program ☐ Hubzone Small Business ☐ EDWOSB ☐ Service-Disabled Veteran-Owned Small Business NAICS: 325412 ☐ 8(A) Size Standard:			
11. Delivery For FOB Destination Unless Block Is Marked ☒ See Schedule		12. Discount Terms		13a. This Contract Is A Rated Order Under DPAS (15 CFR 700) ☐ RFQ ☐ IFB ☒ RFP		13b. Rating NONE	
15. Deliver To SEE SCHEDULE Code				16. Administered By ACC NJ BLDG 10 PHIPPS RD PICATINNY ARSENAL, NJ 07806-5000 Code W15QKN			
17a. Contractor/Offeror Code (b) (6) Facility GLAXOSMITHKLINE LLC 5 MOORE DR RESEARCH TRIANGLE PARK, NC 27709-0143 Telephone No.				18a. Payment Will Be Made By Code HQ0304 DEFENSE FINANCE & ACCTING SERVICE DFAS COLUMBUS DFAS-JAIQBAC/CO PO BOX 182317 COLUMBUS OH 43218-2317			
☐ 17b. Check If Remittance Is Different And Put Such Address In Offer				☐ 18b. Submit Invoices To Address Shown In Block 18a Unless Block Below Is Checked ☐ See Addendum			
19. Item No.	20. Schedule Of Supplies/Services			21. Quantity	22. Unit	23. Unit Price	24. Amount
	SEE SCHEDULE						
(Use Reverse and/or Attach Additional Sheets As Necessary)							
25. Accounting And Appropriation Data SEE CONTRACT ADMINISTRATION DATA						26. Total Award Amount (For Govt. Use Only) \$342,000,000.00	
☐ 27a. Solicitation Incorporates By Reference FAR 52.212-1, 52.212-4, FAR 52.212-3 And 52.212-5 Are Attached. Addenda ☐ Are ☐ Are Not Attached.							
☒ 27b. Contract/Purchase Order Incorporates By Reference FAR 52.212-4, FAR 52.212-5 Is Attached. Addenda ☐ Are ☒ Are Not Attached.							
☒ 28. Contractor Is Required To Sign This Document And Return 2 Copies To Issuing Office. Contractor Agrees To Furnish And Deliver All Items Set Forth Or Otherwise Identified Above And On Any Additional Sheets Subject To The Terms And Conditions Specified.						☐ 29. Award Of Contract: Ref. _____ Offer Dated _____. Your Offer On Solicitation (Block 5), Including Any Additions Or Changes Which Are Set Forth Herein, Is Accepted As To Items:	
30a. Signature Of Offeror/Contractor				31a. United States Of America (Signature Of Contracting Officer) /SIGNED/			
30b. Name And Title Of Signer (Type Or Print)		30c. Date Signed		31b. Name Of Contracting Officer (Type Or Print) (b) (6)		31c. Date Signed 2020JUL30	

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Standard Form 1449 (Rev. 2/2012)
Prescribed By GSA-FAR (48 CFR) 53.212

19. Item No.	20. Schedule Of Supplies/Services	21. Quantity	22. Unit	23. Unit Price	24. Amount

32a. Quantity In Column 21 Has Been

☐ Received ☐ Inspected ☐ Accepted, And Conforms To The Contract, Except As Noted: _____

32b. Signature Of Authorized Government Representative		32c. Date	32d. Printed Name and Title of Authorized Government Representative	
32e. Mailing Address of Authorized Government Representative			32f. Telephone Number of Authorized Government Representative	
			32g. E-Mail of Authorized Government Representative	
33. Ship Number		34. Voucher Number	35. Amount Verified Correct For	36. Payment
☐ Partial	☐ Final			☐ Complete ☐ Partial ☐ Final
38. S/R Account No.	39. S/R Voucher Number	40. Paid By		
41a. I Certify This Account Is Correct And Proper For Payment		42a. Received By (Print)		
41b. Signature And Title Of Certifying Officer		41c. Date	42b. Received At (Location)	
			42c. Date Rec'd (YY/MM/DD)	42d. Total Containers

Standard Form 1449 (Rev. 2/2012) Back

CONTINUATION SHEET	Reference No. of Document Being Continued W15QKN-20-C-0048 PIIN/SHIN MOD/AMD	Page 2 of 32
Name of Offeror or Contractor: GLAXOSMITHKLINE LLC		

SUPPLEMENTAL INFORMATION

Buyer Name: (b) (6)
 Buyer Office Symbol/Telephone Number: CCNJ-IC/(b) (6)
 Type of Contract 1: Firm Fixed Price
 Kind of Contract: Other
 Type of Business: Large Business Performing in U.S.
 Surveillance Criticality Designator: A
 Contract Expiration Date: 2021FEB28

*** End of Narrative A0000 ***

Executive Summary

Background:

The U.S Army Contracting Command - New Jersey (CCNJ), on behalf of Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) and the Biomedical Advanced Research and Development Authority (BARDA), is awarding this contract for the purchase of GlaxoSmithKline's (GSK's) proprietary Adjuvant System 03 (AS03) to support the US Department of Health and Human Services (HHS), through Operation Warp Speed and the Department of Defense (DOD) requirement to procure mass quantities of COVID- 19 vaccines from multiple vendors to support military locations and personnel throughout the Continental United States (CONUS) and outside the Continental United States (OCONUS). To advance the US response to COVID- 19, requirements and technology continue to be identified that are crucial to addressing the public health emergency. Procurement of the products and technology, leading to obtaining sufficient vaccine dosages to vaccinate the US population, will enable the US to bring to bear the most effective measures to defeat the threat of COVID-19.

The following has been updated from the applicable RFP (W15QKN-20-R-0141):

1. Section B has been updated to include Price information.
2. Updated Clauses under Special Contract Requirements to include PREP Act, Third Party Use of AS03, Excusable Delays Due to COVID-19, Payments, and Press Release.
3. Representations, certifications, and other statements of Offerors or respondents of the solicitation are hereby incorporated into the contract by reference.
4. Attachments have been updated to include the following documents:
 a) Attachment 0003 - GSK Small Business Subcontracting Plan
5. The GSK Small Business Subcontracting Plan, dated 15 January 2020 is hereby incorporated into the contract (see Attachment 0003).

*** END OF NARRATIVE A0001 ***

Name of Offeror or Contractor: GLAXOSMITHKLINE LLC

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
	SUPPLIES OR SERVICES AND PRICES/COSTS				
0001	COVID VACCINES NSN: 9999-99-999-9999				
0001AA	<u>ADJUVANT SYSTEM 03 (AS03)</u> COMMODITY NAME: COVID VACCINES CLIN CONTRACT TYPE: Firm Fixed Price PRON: JP0EB73684 PRON AMD: 01 ACRN: AA PSC: 6505 <u>Packaging and Marking</u> <u>Inspection and Acceptance</u> INSPECTION: Origin ACCEPTANCE: Origin <u>Deliveries or Performance</u> DOC SUPPL <u>REL CD</u> <u>MILSTRIP</u> <u>ADDR</u> <u>SIG CD</u> <u>MARK FOR</u> <u>TP CD</u> 001 W56HXN00207002 75A501 J 3 <u>DEL REL CD</u> <u>QUANTITY</u> <u>DEL DATE</u> 001 Exemption (b)(4) Exemption (b)(4) FOB POINT: Origin SHIP TO: (75A501) OFFICE OF ACQ MGMT POLICY HUBERT HUMPHREY BLDG 200 INDEPENDENCE AVENUE SW ROOM 336E WASHINGTON,DC,20201 Exemption (b)(4) (End of narrative F001)	Exemption (b)(4)	EA	\$ _____ Exemption (b)(4)	\$ _____ Exemption (b)(4)
0001AB	<u>ADJUVANT SYSTEM 03 (AS03)</u> COMMODITY NAME: COVID Vaccines CLIN CONTRACT TYPE: Firm Fixed Price PRON: JP0EB73686 PRON AMD: 01 ACRN: AB	Exemption (b)(4)	EA	\$ _____ Exemption (b)(4)	\$ _____ Exemption (b)(4)

Name of Offeror or Contractor: GLAXOSMITHKLINE LLC

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
	PSC: 6505 <u>Packaging and Marking</u> <u>Inspection and Acceptance</u> INSPECTION: Origin ACCEPTANCE: Origin <u>Deliveries or Performance</u> DOC SUPPL <u>REL CD</u> <u>MILSTRIP</u> <u>ADDR</u> <u>SIG CD</u> <u>MARK FOR</u> <u>TP CD</u> 001 W56HXM00207001 75A501 J 3 <u>DEL REL CD</u> <u>QUANTITY</u> <u>DEL DATE</u> 001 Exemption (b)(4) Exemption (b)(4) FOB POINT: Origin SHIP TO: (75A501) OFFICE OF ACQ MGMT POLICY HUBERT HUMPHREY BLDG 200 INDEPENDENCE AVENUE SW ROOM 336E WASHINGTON, DC, 20201 Exemption (b)(4) (End of narrative F001)				
0002	<u>CONTRACT DATA REQUIREMENTS LIST</u> The ELIN below is associated with the Data Item numbers in the Contract Data Requirements List (CDRL, DD 1423), in Section J. Reference individual CDRLs for applicable instructions and delivery dates. (End of narrative A001)				
A001	<u>DD1423 CDRLS A001 THROUGH A007</u> SERVICE REQUESTED: DATA ITEMS CLIN CONTRACT TYPE: Firm Fixed Price <u>Inspection and Acceptance</u> INSPECTION: Destination ACCEPTANCE: Destination	1	LO		\$ ** NSP **

Name of Offeror or Contractor: GLAXOSMITHKLINE LLC

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
	Deliveries or Performance DLVR SCH REL CD 001 QUANTITY 1 PERF COMPL DATE SEE DD FORM 1423				

CONTINUATION SHEET

Reference No. of Document Being Continued

PIIN/SHIN

W15QKN-20-C-0048

MOD/AMD

Page 6 of 32

Name of Offeror or Contractor: GLAXOSMITHKLINE LLC

DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

STATEMENT OF WORK

cGMP Adjuvant Commercial Scale Bulk Lot(s)

And

Fill-Finish of Adjuvant in (b) (4)

C.1 Scope. The Department of Defense and the Department of Health and Human Services (HHS) in support of the national emergency response to the Coronavirus Disease 2019 (COVID-19) requires the production of AS03 Adjuvant on a commercial item basis, to support doses of a vaccine to prevent the general population from developing COVID-19.

C.1.1 Background. The United States Department of Health and Human Services (HHS) continuously monitors emerging infectious disease risk and prepares to respond to the threat of novel emerging infectious disease outbreaks in the United States. HHS is responding to an outbreak of respiratory disease caused by a novel coronavirus that was first detected in China and which has now spread to worldwide, including in the United States. The virus has been named SARS-CoV-2 and the disease it causes has been named coronavirus disease 2019 (abbreviated COVID-19).

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a "https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-%282005%29-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-%282019-ncov%29" (PHEIC). On January 31, Health and Human Services Secretary Alex M. Azar II declared a public health emergency (PHE) for the United States to aid the nations healthcare community in responding to COVID-19. On March 11, "https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020" characterized COVID-19 as a pandemic. On March 13, the President of the United States declared the COVID-19 outbreak a "https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/" . Vaccination is often the most effective measure for the control of infectious diseases. As part of HHS preparedness and response activities, HHS seeks to purchase AS03 adjuvant. AS03 adjuvant administration with vaccine antigen improves immunogenicity and achieves antigen dose-sparing.

C.2 Objectives: The Contractor shall manufacture and fill-finish a total of (b) (4) of AS03 adjuvant. This shall consist of (b) (4) for delivery no later than (b) (4) and (b) (4) for delivery no later than (b) (4) . (b) (4)

C.3. REQUIREMENTS

The contractor shall supply (b) (4) no later than (b) (4) 1 and (b) (4) for delivery no later than (b) (4) .

C.3.1 The contractor shall complete the following in support of cGMP Adjuvant: Commercial Scale Bulk Lot(s):

- Manufacture the bulk adjuvant (b) (4) equivalents) at commercial scale according to current Good Manufacturing Practices (cGMP) under 21 CFR parts 210, 211, and 600, as applicable, and store at appropriate conditions during lot release testing
- Make available batch records for review by HHS
- Execute lot release product testing of bulk adjuvant

C.3.2 The contractor shall complete Fill-finish of Adjuvant in (b) (4)

- Fill-finish adjuvant in final containers (b) (4)
- Fill-finish activities of adjuvant shall be carried out at facilities in compliance with FDA-cGMP guidelines.
- Full release testing of the fill-finished adjuvant (AS03) should be performed. (b) (4)

C.3.3 Storage and Stability: (b) (4)

C.3.4 Product Acceptance:

- The contractor will be paid for product (b) (4)

CONTINUATION SHEET	Reference No. of Document Being Continued		Page 7 of 32
	PIIN/SHIN	MOD/AMD	

W15QKN-20-C-0048

Name of Offeror or Contractor: GLAXOSMITHKLINE LLC

b. Contractor will retain full responsibility for storing and maintaining product [Redacted] Exemption (b)(4)

c. Contractor will label and release labeled product upon direction of the USG

d. Contractor will enter into an agreement with third party to support transfer of adjuvant to the third party. (b) (4)

[Redacted]

[Redacted]

[Redacted]

C.3.5 AS03 Adjuvant Product Container Labeling: The contractor shall label and/or package final adjuvant product in alignment with the requirements of the regulatory authorities (FDA).

C.3.6 [Redacted] Exemption (b)(4)

[Redacted]

[Redacted]

[Redacted]

C.4 Reporting Requirements:

a. A Quality Assessment Report should be submitted within 30 days of award for Government review (DI-QCIC-81187(Tailored)).

b. Monthly Teleconferences and Communication: The contractor shall conduct monthly teleconferences with the Government throughout the performance of the Agreement to discuss tasks accomplished and direction for the upcoming tasks. The Government anticipates reducing the teleconferences once the manufacturing tasks begin. Awardee shall provide agendas and read-ahead material as required one day prior to the meetings and shall provide minutes of each meeting to the Government. Monthly progress reports will include baseline and updated project timelines, milestones and summaries of product manufacturing and testing. Awardee shall include key subcontractors as attendees at these teleconferences when applicable. The Awardee shall provide meeting minutes within three (3) business days after each formal scheduled meeting/teleconference conducted with the Government ((DI-ADMN-81250(Tailored))).

c. In addition to the monthly meetings, additional ad hoc meetings to address specific issues or to convey time-sensitive updates or scientific data related to the program will be held ((DI-ADMN-81250(Tailored))).

d. Incident Report. The contractor shall report any incident including any involving critical deviations, such as out of specification (OOS) results, or other product issues shall be reported to the USG within 3 calendar days. Notify the Technical Point of Contact (TPOC) within one day of incident. A written summary report shall be submitted within three (3) business days of an incident, to include what happened, what was the impact, if there are any available corrective actions and a time line for when the corrective actions would be in place ((DI-MGMT-82071(Tailored))).

e. Contract Summary Report shall be submitted 30 calendar days before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP (DI-ADMN-80447A). The Reports shall contain manufacturing process description including:

- batch number
- date and location of manufacture (including building, room, line number)
- shelf life
- description of process/testing
- final production volume
- complete list of analytical tests performed and results to be agreed between contractor and the USG in advance of preparation of the report
- Certificate(s) of Analysis
- Certificate(s) of Current Good Manufacturing Practices (cGMP) Conformity
- Any critical deviations
- Final status, e.g., released, etc.
- Storage bag, vial, and container closure details
- Photos including USG Property labels

a. 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 submit a Product Development Source Material Report within one month of contract award. The contractor shall also, within 30 days of substantive changes are made to sources and/or materials, or on the 6th month contract anniversary. The contractor shall update the Dose Tracking Template weekly during manufacturing. The Contractor

CONTINUATION SHEET	Reference No. of Document Being Continued W15QKN-20-C-0048 PIIN/SHN MOD/AMD	Page 8 of 32
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Name of Offeror or Contractor: GLAXOSMITHKLINE LLC

will provide manufacturing reports and manufacturing dose tracking projections/actuals utilizing the COVID-19 Dose Tracking Templates or similar, on any contract/agreement that is manufacturing product, including product for clinical trial use. manufacturing campaigns and daily during response operations (where a Public Health Emergency has been declared) and COVID-19 response, with the first deliverable submission within 15 days of award/modification. Updates to be provided weekly in advance of commercial-scale manufacturing and daily once material for use in response operations begins manufacture. 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, the contractor must address all concerns raised by BARDA in writing a Product Development and Source Material report to be submitted via spreadsheet; Dose Tracking can be completed via spreadsheet or other format (e.g. XML or JSON) as agreed to by USG and company (DI-SESS-81309).

b. 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, and within 30 business days after a substantive location or capabilities change. The contractor shall 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 PHEIC by the WHO (DI-ADMN-80447A).

C.5 Period of Performance: Deliveries are due no later than Exemption (b)(4) or Exemption (b)(4) as described above.

C.6 Inspection:

C.6.1 The TPOC is a duly authorized representative of the Government and is responsible for the inspection and/or acceptance of all items/activities to be delivered and/or completed under this agreement. The parties acknowledge that acceptance may depend on the compliance with FDA regulations at 21 CFR 600-680 regarding the BLA, cGMP regulations at 21 CFR 210, 211, and other FDA regulations. The COR reserves the right, prior to acceptance, to consult with FDA under its authority under Public Law 115-92 to determine compliance of the material to be delivered. To this end, contractor agrees to provide a letter to FDA authorizing the Government to engage in dialog with FDA about the ultimate compliance of this product prior to acceptance.

C.7 Packaging and Marking: The contractor shall package Exemption (b)(4).

C.8 Transportation: Exemption (b)(4)

C.9 Government Technical Point of Contact

(b) (6)
BARDA
(b) (6)

*** END OF NARRATIVE C0001 ***

CONTINUATION SHEET	Reference No. of Document Being Continued W15QKN-20-C-0048 PIIN/SIIN MOD/AMD	Page 9 of 32
Name of Offeror or Contractor: GLAXOSMITHKLINE LLC		

INSPECTION AND ACCEPTANCE

	<u>Regulatory Cite</u>	<u>Title</u>	<u>Date</u>
1	52.246-2	INSPECTION OF SUPPLIES--FIXED-PRICE	AUG/1996
2	52.246-16	RESPONSIBILITY FOR SUPPLIES	APR/1984

CONTINUATION SHEET	Reference No. of Document Being Continued W15QKN-20-C-0048 PIIN/SIIN MOD/AMD	Page 10 of 32
Name of Offeror or Contractor: GLAXOSMITHKLINE LLC		

DELIVERIES OR PERFORMANCE

	Regulatory Cite	Title	Date
1	52.247-29	F.O.B. ORIGIN	FEB/2006

Supply Chain Resiliency Plan

The contractor shall develop and submit within 30 calendar days of 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 Officer or the Contracting 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 of contract 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

CONTINUATION SHEET	Reference No. of Document Being Continued W15QKN-20-C-0048 PIIN/SHIN MOD/AMD	Page 11 of 32
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Name of Offeror or Contractor: GLAXOSMITHKLINE LLC

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

- o Within month of contract award
- o Within 30 days of substantive changes are made to sources and/or materials
- o 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

Access and General Protection/Security Policy and Procedures

This standard language text is applicable to ALL employees working on critical information related to Operation Warp Speed (OWS), and to those with an area of performance within a Government controlled installation, facility or area. Employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The performer also shall provide all information required for background checks necessary to access critical information related to OWS, and to meet Government installation access requirements to be accomplished by installation Director of Emergency Services or Security Office. The workforce must comply with all personnel identity verification requirements as directed by the Government and/or local policy. In addition to the changes otherwise authorized by the changes clause of this agreement, should the security status of OWS change the Government may require changes in performer security matters or processes. 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.

Operational Security (OPSEC)

The performer shall develop an OPSEC Standard Operating Procedure (SOP)/Plan within ninety (90)-calendar-days of project award to be reviewed and approved by the responsible Government OPSEC officer. This plan will be submitted to the COR for coordination of approvals. This SOP/Plan will include identifying the critical information related to this contract, why it needs to be protected, where it is located, who is responsible for it, and how to protect it.

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 Government 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:

CONTINUATION SHEET	Reference No. of Document Being Continued		Page 12 of 32
	PIIN/SHN	MOD/AMD	

W15QKN-20-C-0048

Name of Offeror or Contractor: GLAXOSMITHKLINE LLC

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 Government for review and approval by Government security subject matter experts. The performance of work under the contract will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:

Security Administration	- 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	- 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	- 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	- identification and marking of sensitive information - access control - storage of information - document control procedures - retention/ destruction requirements
Information Technology/Cyber Security Policies and Procedures	- 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 - system document control - system backup - system disaster recovery - incident response

CONTINUATION SHEET	Reference No. of Document Being Continued W15QKN-20-C-0048 PIIN/SHN MOD/AMD	Page 13 of 32
Name of Offeror or Contractor: GLAXOSMITHKLINE LLC		

system audit procedures
property accountability

2. Site Security Master Plan

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.

3. Site Threat / Vulnerability / Risk Assessment

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.

4. Physical Security

Description:

- | | |
|---|---|
| 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. 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. |

CONTINUATION SHEET	Reference No. of Document Being Continued W15QKN-20-C-0048 PIIN/SHIN MOD/AMD	Page 14 of 32
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Name of Offeror or Contractor: GLAXOSMITHKLINE LLC

	k) Physical access controls should present a layered approach to critical assets within the facility.
Employee/Visitor Information	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	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	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	a) Conduct new employee security awareness training. b) Conduct and maintain records of annual security awareness training.
Security Management	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	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	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

CONTINUATION SHEET	Reference No. of Document Being Continued		Page 15 of 32
	PIIN/SIIN	MOD/AMD	

W15QKN-20-C-0048

Name of Offeror or Contractor: GLAXOSMITHKLINE LLC

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	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	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	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	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.

CONTINUATION SHEET	Reference No. of Document Being Continued		Page 16 of 32
	PIIN/SHN	MOD/AMD	

W15QKN-20-C-0048

Name of Offeror or Contractor: GLAXOSMITHKLINE LLC

- 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 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.
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 Government Security Team 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.

*** END OF NARRATIVE F0001 ***

CONTRACT ADMINISTRATION DATA

LINE	PRON/ AMS CD/ MIPR/	OBLG	JO NO/			OBLIGATED
ITEM	GFEBs ATA	STAT	ACCT ASSIGN	ACRN		AMOUNT
0001AA	JP0EB73684	2	S.0074658.5.10.2	AA	\$	Exemption (b)(4)
0001AB	JP0EB73686	2	S.0074658.5.10.1	AB	\$	Exemption (b)(4)
					TOTAL	\$ 342,000,000.00

ACRN	ACCOUNTING CLASSIFICATION					OBLIGATED
ITEM	ACRN	EDI/SFIS	ACCOUNTING CLASSIFICATION			AMOUNT
AA	021	202020212040	A5XAH 643627E79RG04	255Y L069073684 S.0074658.5.10.2	021001	\$ Exemption (b)(4)
AB	021	202020212040	A5XAH 643627E79RG04	255Y L069073686 S.0074658.5.10.1	021001	\$ Exemption (b)(4)
					TOTAL	\$ 342,000,000.00

LINE	ITEM	ACRN	EDI/SFIS	ACCOUNTING CLASSIFICATION		
0001AA	AA	021	202020212040	A5XAH 643627E79RG04	255Y L069073684 S.0074658.5.10.2	021001
0001AB	AB	021	202020212040	A5XAH 643627E79RG04	255Y L069073686 S.0074658.5.10.1	021001

Regulatory Cite	Title	Date
1 252.232-7006	WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS	DEC/2018
(a) Definitions. As used in this clause--		

"Department of Defense Activity Address Code (DoDAAC)" is a six position code that uniquely identifies a unit, activity, or organization.

"Document type" means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

"Local processing office (LPO)" is the office responsible for payment certification when payment certification is done external to the entitlement system.

"Payment request" and "receiving report" are defined in the clause at 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(b) Electronic invoicing. The WAWF system provides the method to electronically process vendor payment requests and receiving reports, as authorized by Defense Federal Acquisition Regulation Supplement (DFARS) 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Contractor shall--

(1) Have a designated electronic business point of contact in the System for Award Management at <https://www.sam.gov> ; and

(2) Be registered to use WAWF at <https://wawf.eb.mil/> following the step-by-step procedures for self-registration available at this Web site.

(d) WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the "Web Based Training" link on the WAWF home page at <https://wawf.eb.mil/> .

(e) WAWF methods of document submission. Document submissions may be via Web entry, Electronic Data Interchange, or File Transfer Protocol.

(f) WAWF payment instructions. The Contractor shall use the following information when submitting payment requests and receiving reports in WAWF for this contract or task or delivery order:

W15QKN-20-C-0048

Name of Offeror or Contractor: GLAXOSMITHKLINE LLC

(1) Document type. The Contractor shall submit payment requests using the following document type(s):

(i) For cost-type line items, including labor-hour or time-and-materials, submit a cost voucher.

(ii) For fixed price line items--

(A) That require shipment of a deliverable, submit the invoice and receiving report specified by the Contracting Officer.

Invoice (Contractor Only)

(B) For services that do not require shipment of a deliverable, submit either the Invoice 2in1, which meets the requirements for the invoice and receiving report, or the applicable invoice and receiving report, as specified by the Contracting Officer.

Invoice as 2-in 1

(iii) For customary progress payments based on costs incurred, submit a progress payment request.

(iv) For performance based payments, submit a performance based payment request.

(v) For commercial item financing, submit a commercial item financing request.

(2) Fast Pay requests are only permitted when Federal Acquisition Regulation (FAR) 52.213-1 is included in the contract.

[Note: The Contractor may use a WAWF "combo" document type to create some Combinations of invoice and receiving report in one step.]

(3) Document routing. The Contractor shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table*

Field Name in WAWF	Data to be entered in WAWF
Pay Official DoDAAC	HQ0337
Issue By DoDAAC	W15QKN
Admin DoDAAC	S3309A
Inspect By DoDAAC	W90ZQ2
Ship To Code	TBD
Ship From Code	TBD
Mark For Code	TBD
Service Approver (DoDAAC)	N/A
Service Acceptor (DoDAAC)	N/A
Accept at Other DoDAAC	N/A
LPO DoDAAC	N/A
DCAA Auditor DoDAAC	N/A
Other DoDAAC(s)	N/A

(4) Payment request. The Contractor shall ensure a payment request includes documentation appropriate to the type of payment request in accordance with the payment clause, contract financing clause, or Federal Acquisition Regulation 52.216-7, Allowable Cost and Payment, as applicable.

(5) Receiving report. The Contractor shall ensure a receiving report meets the requirements of DFARS Appendix F.

(g) WAWF point of contact.

(1) The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

(b) (6)

(2) Contact the WAWF helpdesk at 866-618-5988, if assistance is needed.

(End of clause)

CONTINUATION SHEET	Reference No. of Document Being Continued PIIN/SIIN W15QKN-20-C-0048 MOD/AMD	Page 19 of 32
Name of Offeror or Contractor: GLAXOSMITHKLINE LLC		

CONTINUATION SHEET	Reference No. of Document Being Continued W15QKN-20-C-0048 PIIN/SHN	Page 20 of 32 MOD/AMD
Name of Offeror or Contractor: GLAXOSMITHKLINE LLC		

SPECIAL CONTRACT REQUIREMENTS
Associated Contractor Agreement (ACA)

In the following clause "Contractor" shall mean "subcontractor/supplier" and

a) It is recognized that success of the Adjuvanted Recombinant COVID-19 Vaccine Development research effort depends in part upon the open exchange of information between the various Associate Contractors involved in the effort. This clause is intended to insure that there will be appropriate coordination and integration of work by the Associate Contractors to achieve complete compatibility and to prevent unnecessary duplication of effort.

By executing this contract, the Contractor assumes the responsibilities of an Associate Contractor. For the purpose of this clause, the term Contractor includes subsidiaries, affiliates, and organizations under the control of the contractor (e.g. subcontractors).

(b) Work under this contract may involve access to proprietary or confidential data from an Associate Contractor. To the extent that such data is received by the Contractor from any Associate Contractor for the performance of this contract, the Contractor hereby agrees that any proprietary information received shall remain the property of the Associate Contractor and shall be used solely for the purpose of the Adjuvanted Recombinant COVID-19 Vaccine Development research effort. Only that information which is received from another contractor in writing and which is clearly identified as proprietary or confidential shall be protected in accordance with this provision. The obligation to retain such information in confidence will be satisfied if the Contractor receiving such information utilizes the same controls as it employs to avoid disclosure, publication, or dissemination of its own proprietary information. The receiving Contractor agrees to hold such information in confidence as provided herein so long as such information is of a proprietary/confidential or limited rights nature.

(c) The Contractor hereby agrees to closely cooperate as an Associate Contractor with the other Associate Contractors on this research effort. This involves as a minimum:

- (1) Maintenance of a close liaison and working relationship;
 - (2) Maintenance of a free and open information network with all Government-identified Associate Contractors;
 - (3) Delineation of detailed interface responsibilities;
 - (4) Entering into a written agreement with the other Associate Contractors setting forth the substance and procedures relating to the foregoing, and promptly providing the Agreements Officer/Procuring Contracting Officer with a copy of same; and,
 - (5) Receipt of proprietary information from the Associate Contractor and transmittal of Contractor proprietary information to the Associate Contractors subject to any applicable proprietary information exchange agreements between associate contractors when, in either case, those actions are necessary for the performance of either.
- (d) In the event that the Contractor and the Associate Contractor are unable to agree upon any such interface matter of substance, or if the technical data identified is not provided as scheduled, GlaxoSmithKline shall promptly notify the JPEO OR BARDA Program Manager. The Government will determine the appropriate corrective action and will issue guidance to the affected Contractor.
- (e) The Contractor agrees to insert in all subcontracts hereunder which require access to proprietary information belonging to the Associate Contractor, a provision which shall conform substantially to the language of this clause, including this paragraph (e).

11.2 (a) The Contractor should enter into Associate Contractor Agreements (ACA) for any portion of the contract requiring joint participation in the accomplishment of the Governments requirement. The agreements should include the basis for sharing information, data, technical knowledge, expertise, and/or resources essential to the integration of the (insert name of the program or project), to ensure the greatest degree of cooperation for the development of the program to meet the terms of the contract. Associate contractors are listed in (g) below.

(b) ACAs should include the following general information:

- (1) Identify the associate contractors and their relationships.
- (2) Identify the program involved and the relevant Government contracts of the associate contractors.
- (3) Describe the associate contractor interfaces by general subject matter.
- (4) Specify the categories of information to be exchanged or support to be provided.
- (5) Include the expiration date (or event) of the ACA.

CONTINUATION SHEET

Reference No. of Document Being Continued

Page 21 of 32

PIIN/SHIN

W15QKN-20-C-0048

MOD/AMD

Name of Offeror or Contractor: GLAXOSMITHKLINE LLC

(6) Identify potential conflicts between relevant Government contracts and the ACA; include agreements on protection of proprietary data and restrictions on employees.

(c) Provide a copy of such agreement to the Contracting Officer for review before execution of the document by the cooperating contractors.

(d) The Contractor is not relieved of any contract requirements or entitled to any adjustments to the contract terms because of a failure to resolve a disagreement with an associate contractor.

(e) Liability for the improper disclosure of any proprietary data contained in or referenced by any agreement rests with the parties to the agreement, and not the Government.

(f) All costs associated with the agreements are included in the negotiated cost of this contract. Agreements may be amended as required by the Government during the performance of this contract.

(g) The following contractors are associate contractors with whom agreements are required:

Contractor	Address	Program/Contract
(b) (4)	(b) (4)	OVS Project Entitled: Adjuvanted Recombinant COVID-19 Vaccine Development
GlaxoSmithKline	(b) (4) (b) (4) (b) (4)	cGMP Adjuvant Commercial Scale Bulk Lot(s) And Fill-Finish of Adjuvant in (b) (4)

MANDATORY OPSEC CLAUSE

Key Personnel

Any key personnel specified in this contract are considered to be essential to work performance. At least thirty (30) calendar days prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than thirty (30) calendar-day notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties. The following individuals are determined to be key personnel:

Exemption (b)(6)

Substitution of Key Personnel

The Contractor agrees to assign to the contract those persons whose resumes/CVs were submitted with the proposal who are necessary to fill the requirements of the contract. No substitutions shall be made except in accordance with this clause.

All requests for substitution must provide a detailed explanation of the circumstance necessitating the proposed substitution, a complete resume for the proposed substitute and any other information requested by the contracting officer to approve or disapprove the proposed substitution. All proposed substitutes must have qualifications that are equal to or higher than the qualifications of the person to be replaced. The contracting officer or authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.

The contractor further agrees to include the substance of this clause in any subcontract, which may be awarded under this contract.

CONTINUATION SHEET	Reference No. of Document Being Continued PIIN/SHIN W15QKN-20-C-0048 MOD/AMD	Page 22 of 32
Name of Offeror or Contractor: GLAXOSMITHKLINE LLC		

Disclosure of Information

Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO in accordance with OWS or other Government policies and/or guidance. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

The Contractor shall comply with all Government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the Governments rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractors employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activitys security or interrupt the continuity of its operations.

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity for submission to any securities exchange on which the Contractors (or its parent corporations) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

Publications and Publicity

The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government.

(a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published.

(b) Unless authorized in writing by the CO, the contractor shall not display Government logos including Operating Division or Staff Division logos on any publications.

(c) The contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies Government approval or endorsement of the product(s) or service(s) provided.

(d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the Government whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part by the U.S. Government under Contract No. XXXX. The US Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon.

Confidentiality of Information

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

CONTINUATION SHEET	Reference No. of Document Being Continued W15QKN-20-C-0048 PIIN/SIIN MOD/AMD	Page 23 of 32
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Name of Offeror or Contractor: GLAXOSMITHKLINE LLC

f. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

All above requirements MUST be passed to all Sub-contractors.

Organizational Conflicts of Interest

Performance under this contract may create an actual or potential organizational conflict of interest such as are contemplated by FAR Part 9.505-General Rules. The Contractor shall not engage in any other contractual or other activities which could create an organizational conflict of interest (OCI). This provision shall apply to the prime Contractor and all sub-Contractors. This provision shall have effect throughout the period of performance of this contract, any extensions thereto by change order or supplemental agreement, and for two (2) years thereafter. The Government may pursue such remedies as may be permitted by law or this contract, upon determination that an OCI has occurred.

The work performed under this contract may create a significant potential for certain conflicts of interest, as set forth in FAR Parts 9.505-1, 9.505-2, 9.505-3, and 9.505-4. It is the intention of the parties hereto to prevent both the potential for bias in connection with the Contractors performance of this contract, as well as the creation of any unfair competitive advantage as a result of knowledge gained through access to any non-public data or third party proprietary information.

The Contractor shall notify the Contracting Officer immediately whenever it becomes aware that such access or participation may result in any actual or potential OCI. Furthermore, the Contractor shall promptly submit a plan to the Contracting Officer to either avoid or mitigate any such OCI. The Contracting Officer will have sole discretion in accepting the Contractors mitigation plan. In the event the Contracting Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the Contractor from participating in contract requirements related to OCI.

Whenever performance of this contract provides access to another Contractors proprietary information, the Contractor shall enter into a written agreement with the other entities involved, as appropriate, in order to protect such proprietary information from unauthorized use or disclosure for as long as it remains proprietary; and refrain from using such proprietary information other than as agreed to, for example to provide assistance during technical evaluation of other Contractors offers or products under this contract. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the CO within fifteen (15) calendar days of execution.

Institutional Responsibility Regarding Investigator Conflicts of Interest

The Institution (includes any Contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under Government contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: <http://www.ecfr.gov/cgi-bin/textidx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=>

bin/textidx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=

As required by 45 CFR Part 94, the Institution shall, at a minimum:

a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. Included are payments and equity interests;

2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or

3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

Significant financial interests do not include the following:

1. Income from seminars, lectures, or teaching, and service on advisory or review panels for Government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and

2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

CONTINUATION SHEET	Reference No. of Document Being Continued W15QKN-20-C-0048 PIIN/SHN MOD/AMD	Page 24 of 32
Name of Offeror or Contractor: GLAXOSMITHKLINE LLC		

- b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any Government funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.
- c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the Government funded research.
- d. Require that each Investigator who is planning to participate in the Government funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for Government funded research. Require that each Investigator who is participating in the Government funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.
- e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to Government funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to Government funded research when the Institution, thorough its designated official(s), reasonably determines that the significant financial interest: Could be affected by the Government funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the Government funded research.
- f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).
- g. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).
- h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.
- i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.
- j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Contractors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the Government funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the Government funded research project.

The Contracting Officer and/or Government may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the Government funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that Government funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

*** END OF NARRATIVE H0001 ***

Prep Act

CONTINUATION SHEET**Reference No. of Document Being Continued****Page 25 of 32**

PIIN/SHIN

W15QKN-20-C-0048

MOD/AMD

Name of Offeror or Contractor: GLAXOSMITHKLINE LLC

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 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 (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) Contractors performance of this Agreement falls within the scope of the Recommended Activities for responding to the COVID-19 public health emergency, to the extent it is in accordance with Section III of the PREP Act Declaration; and

(iii) Contractor is a Covered Person to the extent it is a person defined in 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 acquisition as long as Contractors activities fall within the terms and conditions of the PREP Act and the PREP Act Declaration.

Third Party Use of AS03

If development of a compatible vaccine is not successful, the USG will retain flexibility to use the adjuvant under the following conditions: The Government agrees that it will notify Contractor of proposed use for any coronavirus pandemic or influenza virus pandemic or associated pandemic preparedness activity clinical trials on U.S. soil as long as such doses are deemed suitable from quality perspective resulting from a changed use purpose such as specifications, labeling, and storage conditions. These terms would apply to orders placed under this Contract until the end of 2021.

The AS03 doses, if not used with the Contractors COVID-19 vaccine collaborator, could be used in future coronavirus and/or influenza virus pandemics or associated pandemic preparedness activities including clinical trials provided that Contractor and the antigen supplier have or put an agreement in place to address key business terms (i.e. IP, Liability, PREP Act, Data Rights, etc.). GSK would commit to review in good faith any potential antigen suppliers proposed by the USG and that any terms agreed would be reasonable and consistent with other similar agreements the Contractor has in place.

Excusable Delays Due to COVID-19

The parties recognize that the global pandemic caused by COVID-19 has had a significant impact on the availability of certain suppliers and other resources necessary to produce certain pharmaceutical and related products, including the AS03 adjuvant. Accordingly, notwithstanding any provision to the contrary herein, the Contractor shall not be liable for default if nonperformance is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence, as contemplated in FAR 52.212-4(f). For avoidance of doubt, occurrences beyond the reasonable control of the Contractor and without its fault or negligence also include supply chain disruptions arising from or related to the COVID-19 pandemic and the availability of materials for performance of this Contract. In the event of an excusable delay caused by a supply chain disruption arising from or related to the COVID-19 pandemic and the availability of materials for performance of this Contract, Contractor shall follow the procedures at FAR 52.212-4(f).

Payments

The parties recognize that there may be potential regulatory requirements and conditions that restrict the Contractors ability to fill-finish, deliver, and/or transfer AS03 to third parties, including (b) (4), as contemplated in this Contract or under future agreements. For avoidance of doubt, and notwithstanding any potential regulatory requirements and conditions specifically as it relates to the approval of labels that may restrict fill-finish, delivery, and/or transfer of AS03 to third parties, the Contractor shall be entitled to payment of the full contract price per dose for each dose that is manufactured and accepted by the Government under the terms of this Contract, regardless of any potential fill-finish, delivery and/or transfer restrictions. The Contractor shall cooperate in good faith with the Government, (b) (4) and/or any third party to address any potential regulatory requirements and conditions, but fill-finish, delivery and/or transfer to a third party shall not be a condition of payment of the per dose price. Material will be stored in the United States.

Press Releases

Contractor shall ensure that the Government has received and approved an advanced copy of any press release to this contract not less than 5 business days prior to the issuance of the press release. If corrective action is required, the Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. Any final press releases shall be submitted to BARDA no later than one (1) calendar day prior to its release.

*** END OF NARRATIVE H0002 ***

CONTINUATION SHEET

Reference No. of Document Being Continued

Page 26 of 32

PIIN/SHIN

W15QKN-20-C-0048

MOD/AMD

Name of Offeror or Contractor: GLAXOSMITHKLINE LLC

CONTRACT CLAUSES

	Regulatory Cite	Title	Date
1	52.204-13	SYSTEM FOR AWARD MANAGEMENT MAINTENANCE	OCT/2018
2	52.204-18	COMMERCIAL AND GOVERNMENT ENTITY CODE MAINTENANCE	JUL/2016
3	52.212-4	CONTRACT TERMS AND CONDITIONS--COMMERCIAL ITEMS	OCT/2018
4	52.232-40	PROVIDING ACCELERATED PAYMENTS TO SMALL BUSINESS SUBCONTRACTORS	DEC/2013
5	252.203-7000	REQUIREMENTS RELATING TO COMPENSATION OF FORMER DOD OFFICIALS	SEP/2011
6	252.203-7002	REQUIREMENT TO INFORM EMPLOYEES OF WHISTLEBLOWER RIGHTS	SEP/2013
7	252.203-7003	AGENCY OFFICE OF THE INSPECTOR GENERAL	AUG/2019
8	252.204-7003	CONTROL OF GOVERNMENT PERSONNEL WORK PRODUCT	APR/1992
9	252.204-7015	NOTICE OF AUTHORIZED DISCLOSURE OF INFORMATION FOR LITIGATION SUPPORT	MAY/2016
10	252.204-7018	PROHIBITION ON THE ACQUISITION OF COVERED DEFENSE TELECOMMUNICATIONS EQUIPMENT OR SERVICES	DEC/2019
11	252.205-7000	PROVISION OF INFORMATION TO COOPERATIVE AGREEMENT HOLDERS	DEC/1991
12	252.209-7004	SUBCONTRACTING WITH FIRMS THAT ARE OWNED OR CONTROLLED BY THE GOVERNMENT OF A TERRORIST COUNTRY	MAY/2019
13	252.225-7012	PREFERENCE FOR CERTAIN DOMESTIC COMMODITIES	DEC/2017
14	252.225-7048	EXPORT-CONTROLLED ITEMS	JUN/2013
15	252.232-7010	LEVIES ON CONTRACT PAYMENTS	DEC/2006
16	252.243-7002	REQUESTS FOR EQUITABLE ADJUSTMENT	DEC/2012
17	252.244-7000	SUBCONTRACTS FOR COMMERCIAL ITEMS	JUN/2013
18	252.247-7023	TRANSPORTATION OF SUPPLIES BY SEA--BASIC	FEB/2019
19	52.212-5	CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS--COMMERCIAL ITEMS	JUN/2020

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(3) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2019) (Section 889(a) (1) (A) of Pub. L. 115-232).

(4) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015)

(5) 52.233-3, Protest After Award (AUG 1996) (31 U.S.C. 3553).

(6) 52.233-4, Applicable Law for Breach of Contract Claim (OCT 2004) (Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the contracting officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

X (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (Jun 2020), with Alternate I (Oct 1995) (41 U.S.C. 4704 and 10 U.S.C. 2402).

X (2) 52.203-13, Contractor Code of Business Ethics and Conduct (Jun 2020) (41 U.S.C. 3509).

 (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (Jun 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)

X (4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (Jun 2020) (Pub. L. 109-282) (31 U.S.C. 6101 note).

 (5) [Reserved].

 (6) 52.204-14, Service Contract Reporting Requirements (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).

 (7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Oct 2016) (Pub. L. 111-117, section

CONTINUATION SHEET

Reference No. of Document Being Continued

PIIN/SHN

W15QKN-20-C-0048

MOD/AMD

Page 27 of 32

Name of Offeror or Contractor: GLAXOSMITHKLINE LLC

743 of Div. C).

X (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (Jun 2020) (31 U.S.C. 6101 note).

X (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (Oct 2018) (41 U.S.C. 2313).

___ (10) [Reserved]

___ (11) (i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (MAR 2020) (15 U.S.C. 657a).

___ (ii) Alternate I (MAR 2020) of 52.219-3.

___ (12) (i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (MAR 2020) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).

___ (ii) Alternate I (MAR 2020) of 52.219-4.

___ (13) [Reserved]

___ (14) (i) 52.219-6, Notice of Total Small Business Set-Aside (MAR 2020) (15 U.S.C. 644).

___ (ii) Alternate I (MAR 2020) of 52.219-6.

___ (iii) Alternate II (Nov 2011) of 52.219-6.

___ (15) (i) 52.219-7, Notice of Partial Small Business Set-Aside (MAR 2020) (15 U.S.C. 644).

___ (ii) Alternate I (MAR 2020) of 52.219-7.

___ (iii) Alternate II (Mar 2004) of 52.219-7.

___ (16) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)).

X (17) (i) 52.219-9, Small Business Subcontracting Plan (Jun 2020) (15 U.S.C. 637(d)(4)).

___ (ii) Alternate I (Nov 2016) of 52.219-9.

___ (iii) Alternate II (Nov 2016) of 52.219-9.

___ (iv) Alternate III (Jun 2020) of 52.219-9.

___ (v) Alternate IV (Jun 2020) of 52.219-9.

___ (18) 52.219-13, Notice of Set-Aside of Orders (MAR 2020) (15 U.S.C. 644(r)).

___ (19) 52.219-14, Limitations on Subcontracting (MAR 2020) (15 U.S.C. 637(a)(14)).

___ (20) 52.219-16, Liquidated Damages--Subcontracting Plan (JAN 1999) (15 U.S.C. 637(d)(4)(F)(i)).

___ (21) 52.219-27, Notice of Total Service-Disabled Veteran-Owned Small Business Set-Aside (MAR 2020) (15 U.S.C. 657 f)

___ (22) 52.219-28, Post Award Small Business Program Rerepresentation (MAR 2020) (15 U.S.C. 632(a)(2)).

___ (i) Alternate I (MAR 2020) of 52.219-28.

___ (23) 52.219-29 Notice of Total Set-Aside for Economically Disadvantaged Women-Owned Small Business (EDWOSB) Concerns (MAR 2020) (15 U.S.C. 637(m)).

___ (24) 52.219-30 Notice of Total Set-Aside for Women-Owned Small Business (WOSB) Concerns Eligible Under the WOSB Program (MAR 2020) (15 U.S.C. 637(m)).

___ (25) 52.219-32, Orders Issued Directly Under Small Business Reserves (MAR 2020) (15 U.S.C. 644(r)).

___ (26) 52.219-33, Nonmanufacturer Rule (MAR 2020) (15 U.S.C. 637(a)(17)).

CONTINUATION SHEET	Reference No. of Document Being Continued W15QKN-20-C-0048 PIIN/SHN MOD/AMD	Page 28 of 32
Name of Offeror or Contractor: GLAXOSMITHKLINE LLC		

- X (27) 52.222-3, Convict Labor (June 2003) (E.O. 11755).
- X (28) 52.222-19, Child Labor Cooperation with Authorities and Remedies (Jan 2020) (E.O. 13126).
- X (29) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
- X (30) (i) 52.222-26, Equal Opportunity (Sep 2016) (E.O. 11246).
- ___ (ii) Alternate I (Feb 1999) of 52.222-26.
- X (31) (i) 52.222-35, Equal Opportunity for Veterans (Jun 2020) (38 U.S.C. 4212).
- ___ (ii) Alternate I (July 2014) of 52.222-35.
- X (32) (i) 52.222-36, Equal Opportunity for Workers with Disabilities (Jun 2020) (29 U.S.C. 793).
- ___ (ii) Alternate I (July 2014) of 52.222-36.
- ___ (33) 52.222-37, Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Jun 2020) (38 U.S.C. 4212).
- X (34) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).
- X (35) (i) 52.222-50, Combating Trafficking in Persons (Jan 2019) (22 U.S.C. chapter 78 and E.O. 13627).
- ___ (ii) Alternate I (Mar 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
- ___ (36) 52.222-54, Employment Eligibility Verification (Oct 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)
- ___ (37) (i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA-Designated Items (May 2008) (42 U.S.C. 6962(c) (3) (A) (ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
- ___ (ii) Alternate I (May 2008) of 52.223-9 (42 U.S.C. 6962(i) (2) (C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
- ___ (38) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (June, 2016) (E.O. 13693).
- ___ (39) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (June, 2016) (E.O. 13693).
- ___ (40) (i) 52.223-13, Acquisition of EPEAT[supreg]-Registered Imaging Equipment (Jun 2014) (E.O.s 13423 and 13514).
- ___ (ii) Alternate I (Oct 2015) of 52.223-13.
- ___ (41) (i) 52.223-14, Acquisition of EPEAT[supreg]-Registered Televisions (Jun 2014) (E.O.s 13423 and 13514).
- ___ (ii) Alternate I (Jun 2014) of 52.223-14.
- ___ (42) 52.223-15, Energy Efficiency in Energy-Consuming Products (Dec 2007) (42 U.S.C. 8259b).
- ___ (43) (i) 52.223-16, Acquisition of EPEAT[supreg]-Registered Personal Computer Products (Oct 2015) (E.O.s 13423 and 13514).
- ___ (ii) Alternate I (Jun 2014) of 52.223-16.
- X (44) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (Jun 2020) (E.O. 13513).
- ___ (45) 52.223-20, Aerosols (June, 2016) (E.O. 13693).
- ___ (46) 52.223-21, Foams (June, 2016) (E.O. 13693).
- ___ (47) (i) 52.224-3, Privacy Training (JAN 2017) (5 U.S.C. 552a).
- ___ (ii) Alternate I (JAN 2017) of 52.224-3.
- ___ (48) 52.225-1, Buy American--Supplies (MAY 2014) (41 U.S.C. chapter 83).
- ___ (49) (i) 52.225-3, Buy American--Free Trade Agreements--Israeli Trade Act (MAY 2014) (41 U.S.C. chapter 83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-

CONTINUATION SHEET	Reference No. of Document Being Continued W15QKN-20-C-0048 PIIN/SHIN MOD/AMD	Page 29 of 32
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Name of Offeror or Contractor: GLAXOSMITHKLINE LLC

283, 110-138, 112-41, 112-42, and 112-43.

- ___ (ii) Alternate I (MAY 2014) of 52.225-3.
- ___ (iii) Alternate II (MAY 2014) of 52.225-3.
- ___ (iv) Alternate III (MAY 2014) of 52.225-3.
- ___ (50) 52.225-5, Trade Agreements (Oct 2019) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).
- ___ (51) 52.225-13, Restrictions on Certain Foreign Purchases (Jun 2008) (E.o.s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
- ___ (52) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Jul 2013) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
- ___ (53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov 2007) (42 U.S.C. 5150).
- ___ (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) (42 U.S.C. 5150).
- ___ (55) 52.229-12, Tax on Certain Foreign Procurements (JUN 2020).
- ___ (56) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
- ___ (57) 52.232-30, Installment Payments for Commercial Items (Jan 2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
- ___ (58) 52.232-33, Payment by Electronic Funds Transfer -- System for Award Management (Oct 2018) (31 U.S.C. 3332).
- ___ (59) 52.232-34, Payment by Electronic Funds Transfer -- Other Than System for Award Management (Jul 2013) (31 U.S.C. 3332).
- ___ (60) 52.232-36, Payment by Third Party (MAY 2014) (31 U.S.C. 3332).
- ___ (61) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).
- ___ (62) 52.242-5, Payments to Small Business Subcontractors (Jan 2017) (15 U.S.C. 637(d) (13)).
- ___ (63) (i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx 1241(b) and 10 U.S.C. 2631).
- ___ (ii) Alternate I (Apr 2003) of 52.247-64.
- ___ (iii) Alternate II (Feb 2006) of 52.247-64.
- (c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or executive orders applicable to acquisitions of commercial items:
 - ___ (1) 52.222-41, Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter 67).
 - ___ (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (MAY 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
 - ___ (3) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards--Price Adjustment (Multiple Year and Option Contracts) (MAY 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
 - ___ (4) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards--Price Adjustment (MAY 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
 - ___ (5) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (MAY 2014) (41 U.S.C. chapter 67).
 - ___ (6) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements (MAY 2014) (41 U.S.C. chapter 67).
 - ___ (7) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015) (Executive Order 13658).

CONTINUATION SHEET	Reference No. of Document Being Continued W15QKN-20-C-0048 PIIN/SIIN MOD/AMD	Page 30 of 32
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Name of Offeror or Contractor: GLAXOSMITHKLINE LLC

___ (8) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).

___ (9) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, as defined in FAR 2.101, on the date of award of this contract, and does not contain the clause at 52.215-2, Audit and Records -- Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractors directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR Subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c) and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause--

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (Jun 2020) (41 U.S.C. 3509).

(ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(iii) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(iv) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).

(v) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR 19.702(a) on the date of subcontract award, the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(vi) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).

(vii) 52.222-26, Equal Opportunity (Sep 2016) (E.O. 11246).

(viii) 52.222-35, Equal Opportunity for Veterans (Jun 2020) (38 U.S.C. 4212).

(ix) 52.222-36, Equal Opportunity for Workers with Disabilities (Jun 2020) (29 U.S.C. 793).

(x) 52.222-37, Employment Reports on Veterans (Jun 2020) (38 U.S.C. 4212).

(xi) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496).

(xii) 52.222-41, Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter 67).

(xiii) (A) 52.222-50, Combating Trafficking in Persons (Jan 2019) (22 U.S.C. 7104(g)).

(B) Alternate I (Mar 2015) of 52.222-50 (22 U.S.C. 7104(g)).

(xiv) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (MAY 2014) (41 U.S.C. chapter 67).

(xv) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements

CONTINUATION SHEET	Reference No. of Document Being Continued W15QKN-20-C-0048 PIIN/SIIN MOD/AMD	Page 31 of 32
Name of Offeror or Contractor: GLAXOSMITHKLINE LLC		

(MAY 2014) (41 U.S.C. chapter 67).

(xvi) 52.222-54, Employment Eligibility Verification (Oct 2015).

(xvii) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015) (Executive Order 13658).

(xviii) 52.222-62 Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).

(xix) (A) 52.224-3, Privacy Training (JAN 2017) (5 U.S.C. 552a).

(B) Alternate I (JAN 2017) of 52.224-3.

(xx) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Jul 2013) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).

(xxi) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.

(xxii) 52.247-64, Preference for Privately-Owned U.S. Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of Clause)

CONTINUATION SHEET	Reference No. of Document Being Continued PIIN/SIIN W15QKN-20-C-0048 MOD/AMD	Page 32 of 32
Name of Offeror or Contractor: GLAXOSMITHKLINE LLC		

LIST OF ATTACHMENTS

<u>List of Addenda</u>	<u>Title</u>	<u>Date</u>	<u>Number of Pages</u>	<u>Transmitted By</u>
Exhibit A	CONTRACT DATA REQUIREMENTS LIST	22-JUL-2020	003	EMAIL
Attachment 0001	DISCLOSURE OF LOBBYING ACTIVITIES		002	EMAIL
Attachment 0002	INME-PIC-IM FORM 3002	01-MAR-2011	002	EMAIL
Attachment 0003	GSK APPROVED SUBCONTRACTING PLAN	15-JAN-2020	012	EMAIL

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1. CONTRACT ID CODE		PAGE OF PAGES 1 89	
2. AMENDMENT/MODIFICATION NO. P00081		3. EFFECTIVE DATE 05-Aug-2020		4. REQUISITION/PURCHASE REQ. NO. SEE SCHEDULE		5. PROJECT NO. (If applicable)	
6. ISSUED BY US ARMY CONTRACTING COMMAND PHIPPS ROAD PICATINNY NJ 07806-5000		CODE W15QKN		7. ADMINISTERED BY (If other than item 6) DCMA ATLANTA 2300 LAKE PARK DRIVE SUITE 300 SMYRNA GA 30080-4091		CODE S1103A	
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) ADVANCED TECHNOLOGY INTERNATIONAL ON BEHALF OF THE NCBCDC 315 SIGMA DR SUMMERVILLE SC 29486-7790				9A. AMENDMENT OF SOLICITATION NO.			
				9B. DATED (SEE ITEM 11)			
				X 10A. MOD. OF CONTRACT/ORDER NO. W15QKN-16-9-1002			
				X 10B. DATED (SEE ITEM 13) 08-Apr-2016			
CODE 1G3V8		FACILITY CODE					
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS							
☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended. Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.							
12. ACCOUNTING AND APPROPRIATION DATA (If required) See Schedule							
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.							
A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.							
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).							
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:							
X D. OTHER (Specify type of modification and authority) IAW the terms and conditions of the OTA.							
E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return <u>1</u> copies to the issuing office.							
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Modification Control Number: martins201688 See "SUMMARY OF CHANGES" for Modification Description.							
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.							
15A. NAME AND TITLE OF SIGNER (Type or print)				16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)			
				TEL: (b) (6) / CONTRACTING OFFICER			
15B. CONTRACTOR/OFFEROR (b) (6) Dolan, Mica Sr. Vice President, Contracts and Procurement Aug 4 2020 (Signature of person authorized to sign)				15C. DATE SIGNED			
				16B. UNITED STATES OF AMERICA BY (b) (6) (Signature of Contracting Officer)			
				16C. DATE SIGNED 05-Aug-2020			

EXCEPTION TO SF 30
APPROVED BY OIRM 11-84

30-105-04

STANDARD FORM 30 (Rev. 10-83)

MULTI-HHS-NIAID-20-2551, 20-2560, 20-2568-A-000153
FAR (48 CFR) 53.243

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION A - SOLICITATION/CONTRACT FORM

The following have been added by full text:

MOD DESCRIPTION - P00081

The purpose of this modification is to:

- 1) Award RPP 20-11, MCDC2011-004 (Janssen Pharmaceuticals, Inc.) via incorporation of the Terms and Conditions below:
- 2) Add incremental funding to the following project:

RPP 20-11, PRE-20-11 (Janssen): \$1,001,650,000.00 via CLIN 0058.
- 3) Incorporate an updated MCDC Award Tracker, listing the cost/fee and ceiling breakouts for each awarded project via MCDC Award Tracker P00081.

The information, redlines, exchanges, comments provided herein are part of ongoing negotiations that the Parties consider to be Government deliberative process and Janssen trade secrets, commercial or financial information. The Parties are sharing this information, redlines, exchanges, comments under the assurance that each Party shall maintain the confidentiality of the information under the Trade Secrets Act, Procurement Integrity Act, other applicable statutes, regulations, rules, case law, contractual provisions, protective orders or otherwise, and as such, the information, redlines, exchanges, comments provided herein are exempt from disclosure under Exemptions 4 and 5 of the Freedom of Information Act ("FOIA").

P00081 Modification to MCDC OTA No. W15QKN-16-9-1002

BETWEEN

JANSSEN PHARMACEUTICALS, INC.
1125 TRENTON-HARBOURTON ROAD
TITUSVILLE, NJ 08560, USA

AND

THE U.S. ARMY CONTRACTING COMMAND – NEW JERSEY
PHIPPS ROAD, BUILDING 9
PICATINNY ARSENAL, NJ 07806-5000

AND

**THE MEDICAL DEFENSE CBRN DEFENSE CONSORTIUM
C/O ADVANCED TECHNOLOGY INTERNATIONAL**

315 SIGMA DRIVE
SUMMERVILLE, SC 29486

CONCERNING

**COVID-19 PANDEMIC-VACCINE RAPID ADVANCED RESEARCH &
DEVELOPMENT (“ARD”) TO LARGE-SCALE MANUFACTURING**

Modification to MCDC OTA No. W15QKN-16-9-1002: P00081

Project Identifier: MCDC2011-004

Requiring Activity: Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND)

Total Amount of the Agreement: \$1,001,650,000

Funds Obligated: \$1,001,650,000

Effective Date of Agreement:

Period of Performance: Contract Award—January 31, 2022 (estimated)

Authority: 10 U.S.C. 2371b, and 10 U.S.C. 2371b(f)

This Agreement is entered into between the United States of America, represented by the Department of Defense ("DoD"), Army Contracting Command-New Jersey; Advanced Technology International ("ATI") as the Consortium Management Firm ("CMF") of the Medical CBRN Defense Consortium; and Janssen Pharmaceuticals, Inc., pursuant to and under U.S. Federal law.

Janssen Pharmaceuticals, Inc.

U.S. Department of Defense

(b) (6)

BY:

(b) (6)

NAME: Peter W. Gerhard
ITS: Agreements Officer, CCNJ-ET

DATE: 04 August 2020

DATE: 05 August 2020

The Medical Defense CBRN Defense
Consortium c/o
Advanced Technology International

BY:

(b) (6)

NAME: Mica Dolan
ITS: VP Contacts and Procurement
DATE: 04 August 2020

Table of Contents

RECITALS	8
Article I. Scope of the Project Agreement	8
SECTION I.1 INTRODUCTION	8
SECTION I.2 DEFINITIONS	9
SECTION I.3 PROTOTYPE PROJECT, MILESTONES, AND PRICING ASSUMPTIONS AND CONDITIONS	14
SECTION I.4 SCOPE OF P00081 MODIFICATION	18
SECTION I.5 PROTOTYPE DELIVERABLES	19
SECTION I.6 FOLLOW-ON PRODUCTION	21
Article II. Term and Termination	21
SECTION II.1 TERM	21
SECTION II.2 TERMINATION	21
SECTION II.3 EXTENSION OF TERM	22
Article III. Project Management, Modifications, and Administration	22
SECTION III.1 MANAGEMENT AND MODIFICATIONS	22
SECTION III.2 PROJECT AGREEMENT ADMINISTRATION	23
Article IV. “PREP ACT” Coverage	24
Article V. Obligation and Payment	25
SECTION V.1 LIMITATION OF LIABILITY	25
SECTION V.2 FIXED PRICE PAYMENT METHOD	25
SECTION V.3 ACCOUNTING SYSTEM REQUIREMENTS	26
SECTION V.4 PAYMENTS AND PAYMENT INSTRUCTIONS	26
SECTION V.5 COMPTROLLER GENERAL ACCESS TO RECORDS	27
Article VI. Disputes	27
Article VII. Confidential Information	28
SECTION VII.1 AUTHORIZED DISCLOSURE	28
SECTION VII.2 EXCLUSIONS	29
SECTION VII.3 TERM	29
Article VIII. Publication and Academic Rights	29
SECTION VIII.1 USE OF INFORMATION	29
SECTION VIII.2 PUBLICATION OR PUBLIC DISCLOSURE OF DATA	29
Article IX. Patent Rights	30
SECTION IX.1 BACKGROUND INTELLECTUAL PROPERTY DISCLOSURES	30
SECTION IX.2 ALLOCATION OF PRINCIPLE RIGHTS	30
SECTION IX.3 INVENTION DISCLOSURE, ELECTION OF TITLE, AND FILING OF PATENT APPLICATION	30
SECTION IX.4 CONDITIONS WHEN THE GOVERNMENT MAY OBTAIN TITLE	32
SECTION IX.5 MINIMUM RIGHTS TO JANSSEN’S CONSORTIUM AND PROTECTION OF JANSSEN’S CONSORTIUM’S RIGHT TO FILE	32
SECTION IX.6 ACTION TO PROTECT JPEO-CBRND’S INTEREST	33
SECTION IX.7 REPORTING ON UTILIZATION OF SUBJECT INVENTIONS	33
SECTION IX.8 MARCH-IN RIGHTS	34
SECTION IX.9 BACKGROUND INFORMATION	35
Article X. Data Rights	35
SECTION X.1 DATA CATEGORIES	37
SECTION X.2 ALLOCATION OF PRINCIPLE RIGHTS	38
SECTION X.3 IDENTIFICATION AND DISPOSITION OF DATA	39
Article XI. Export Control	40

Article XII. Government Furnished Property	40
Article XIII. Civil Rights Act	40
Article XIV. Small Business Affiliation	40
Article XV. Antitrust.....	40
Article XVI. Security and Operations Security (“OPSEC”)	40
Article XVII. Safety.....	41
Article XVIII. Representations and Warranties	41
SECTION XVIII.1 REPRESENTATIONS AND WARRANTIES OF ALL PARTIES	41
SECTION XVIII.2 LIMITATIONS	41
Article XIX. General Provisions	41
SECTION XIX.1 FEES	41
SECTION XIX.2 WAIVER.....	41
SECTION XIX.3 SECTION HEADINGS	42
SECTION XIX.4 SEVERABILITY	42
SECTION XIX.5 EXCUSABLE DELAY	42
SECTION XIX.6 REGULATORY RIGHTS.....	43
SECTION XIX.7 FAILURE TO PROVIDE PROTOTYPE PRODUCT	44
SECTION XIX.8 RADIOACTIVE MATERIALS.....	45
SECTION XIX.9 RECOMBINANT DNA.....	45
SECTION XIX.10 REQUIRED COMPLIANCE FOR USE OF LABORATORY ANIMALS	45
SECTION XIX.11 REQUIRED COMPLIANCE FOR USE OF HUMAN SUBJECTS	45
SECTION XIX.12 REQUIRED COMPLIANCE FOR USE OF HUMAN ANATOMICAL SUBSTANCES.....	45
SECTION XIX.13 COMPLIANCE WITH GOOD MANUFACTURING PROCESSES	45
SECTION XIX.14 REGISTRATION WITH SELECT AGENT PROGRAM	46
SECTION XIX.15 DUTY FREE ENTRY	46
Article XX. Assignment of Agency	46
Article XXI. Order of Precedence.....	46
Article XXII. Execution	47
Article XXIII. Antibribery and Anti-Corruption	47
Article XXIV. Inspection, Acceptance, & Delivery	47
Article XXV. Foreign Access to Technology	50
Article XXVI. Government Observer in Recipient Facility	51
Article XXVII. Reporting Matters Involving Fraud, Waste and Abuse.....	51
Article XXVIII. Prohibition on Contractor Involvement with Terrorist Activities.....	51
Article XXIX. Survival.....	51
SECTION XXIX.1 CLOSE-OUT PROCEDURE.....	51

RECITALS

This Project Agreement is an “Other Transaction for Prototype” pursuant to 10 U.S.C. § 2371b. For the avoidance of doubt, this Project Agreement is not a procurement contract, grant, or cooperative agreement. The Federal Acquisition Regulation (“FAR”) and the Defense Federal Acquisition Regulation Supplement (“DFARS”) do not apply to this Project Agreement except for any provision expressly referenced herein.

This Project Agreement is being entered between the United States Government, as represented by the U.S. Department of Defense, Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (“JPEO-CBRND”), the U.S. Department of Health and Human Services, Biomedical Advanced Research and Development Authority (“BARDA”); and Janssen Pharmaceuticals, Inc. on behalf of itself and the Janssen Consortium Members, as defined in 1.2 herein.

Whereas the Public Readiness and Emergency Preparedness Act (“PREP Act”) authorizes the Secretary of Health and Human Services (the “Secretary”) to issue a Declaration to provide liability immunity to certain individuals and entities (“Covered Persons”) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (“Covered Countermeasures”).

Whereas the Secretary has issued a PREP Act Declaration on 10 March 2020, as amended, (herein referred to as “Secretary’s COVID-19 PREP Act Declaration”) and declared that the spread of novel Coronavirus (“SARS-CoV-2”) or a virus mutating therefrom and the resulting disease, Coronavirus Disease (“COVID-19”), constitutes a public health emergency.

Now therefore, the Parties agree as follows:

Article I. Scope of the Project Agreement

Article I of the Agreement is hereby superseded by the following terms and conditions of this Project Agreement.

Section I.1 Introduction

The development of a safe and effective SARS-CoV-2 vaccine is considered critical to contain the current COVID-19 pandemic and declared health emergency, and help to prevent future outbreaks. Working with its partners under BARDA OTA No. HHSO100201700018C (“BARDA OTA”), Janssen has generated Ad26.COV2.S, an adenovirus Type 26 (“Ad26”) replication-incompetent recombinant vector expressing a stabilized SARS-CoV-2 vaccine, Ad26.COV2.S, recombinant (“Ad26.COV2.S”). Ad26.COV2.S has been shown to induce high levels of neutralizing antibodies against SARS-CoV-2 after immunization with a single dose of the vaccine candidate in different animal species. Furthermore, efficacy against SARS-CoV-2 infection has been shown in

Syrian hamsters. Additional preclinical results will be generated over the coming months, e.g. protection in Non-Human Primates (“NHP”). Clinical studies will start soon with the goal to demonstrate safety, immunogenicity and efficacy. Ad26.COVS.2 will be manufactured on PER.C6® TetR cells and large-scale manufacturing will be needed to address the large demand for vaccination of large parts of the population.

The following efforts, while integral to the overall Ad26.COVS.2 program, are outside the scope of this Project Agreement:

- Chemistry, Manufacturing, and Controls (“CMC”) development, including manufacturing of Drug Substance (“DS”) and Drug Product (“DP”) and nonclinical and clinical development of Ad26.COVS.2, partially funded by BARDA OTA No. HHSO100201700018C;
- Large-scale manufacturing DS capacity established at a Janssen facility in Leiden, Netherlands, as well as with a Contracting Manufacturing Organization (“CMO”), Emergent BioSolutions, which is located in Rockville, MD;
- DP capacity established at Catalent in Bloomington, IN;
- Facility construction and modification, equipment purchase, qualification, and technical transfer activities to manufacture both DS and DP domestically;
- Preparation and submission of applications for an Emergency Use Authorization (“EUA”) and Biologics License Application (“BLA”); and
- Monitoring, reporting, and healthcare worker, public education, and communications activities related to EUA distribution, which will be discussed and determined during the pre-EUA discussion period, as defined in applicable guidance documents.

For the avoidance of doubt, Catalent and Emergent, described above, are not considered subcontractors under this Project Agreement.

Article I, Section 2 of the Agreement, hereby adopts the following terms and conditions of the Project Agreement. If there is a conflict between the Agreement and the Project Agreement, the Agreement is hereby superseded by the following terms and conditions of this Project Agreement.

Section I.2 Definitions

Academic Research Institution: This term/condition is not applicable to this Project Agreement, and it is hereby self-deleting from the MCD C Base OTA No. W15QKN-16-9-1002.

Affiliate: Any entity that controls, is controlled by, or is under common control with, a Party to this Project Agreement. In this context, “control” shall mean (1) ownership by one entity, directly or indirectly, of at least fifty percent (50%) of the voting stock of another entity; or (2) power of one entity to direct the management or policies of another entity, by contract or otherwise.

Agreement: Reference back to Article I, Section 2 of the MDCDC Base OTA No. W15QKN-16-9-1002.

Agreements Officer (“AO”): Reference back to Article I, Section 2 of the MDCDC Base OTA No. W15QKN-16-9-1002.

Agreements Officer’s Representative (“AOR”): Reference back to Article I, Section 2 of the MDCDC Base OTA No. W15QKN-16-9-1002.

Background Invention: Background Invention means any Invention, or improvement to any Invention, other than a Subject Invention, that was conceived, designed, developed, produced, and/or reduced to practice prior to performance of the Agreement or this Project Agreement, or outside the scope of work performed under the Agreement or this Project Agreement.

Basket: This term/condition is not applicable to this Project Agreement, and it is hereby self-deleting from the MDCDC Base OTA No. W15QKN-16-9-1002.

Cash Contribution: This term/condition is not applicable to this Project Agreement, and it is hereby self-deleting from the MDCDC Base OTA No. W15QKN-16-9-1002.

Confidential Information: Reference back to Article VIII, Section 1 of the MDCDC Base OTA No. W15QKN-16-9-1002.

Consortium Management Firm (“CMF”): Reference back to Article I, Section 2 of the MDCDC Base OTA No. W15QKN-16-9-1002.

Cost Share: This term/condition is not applicable to this Project Agreement, and it is hereby self-deleting from the MDCDC Base OTA No. W15QKN-16-9-1002.

Contracting Activity: Reference back to Article I, Section 2 of the MDCDC Base OTA No. W15QKN-16-9-1002.

Date of Completion: The date on which the period of performance ends.

Data: Recorded information first created in performance of the Project, regardless of form or method of recording, which includes but is not limited to, technical data and software, but does not include Subject Inventions, production/manufacturing know-how, trade secrets, clinical data, or financial, administrative, cost, pricing or management information.

Deliverable(s): Any documentation (e.g. report, Executive Summary, Letter) given to the Government by Janssen to provide the Government with insight into “Janssen’s Manufacturing Capability” (as defined herein) as described in the second column of Table 1-5 in Article I, Section 5 under the heading “Deliverables.”

Development: This term/condition is not applicable to this Project Agreement, and it is hereby self-deleting from the MCDL Base OTA No. W15QKN-16-9-1002.

Disclosing Party: Reference back to Article VIII, Section 1 of the MCDL Base OTA No. W15QKN-16-9-1002.

Effective Date: The date of execution of this Project Agreement by the Parties. If this Project Agreement is executed in counterparts, the Effective Date shall be the date of the last signature.

Field: Means the development and use of a vaccine to protect against COVID-19 disease caused by SARS-CoV-2 infection.

Government: Reference back to Article I, Section 2 of the MCDL Base OTA No. W15QKN-16-9-1002. Also referred to as "USG."

Government Fiscal Year: Reference back to Article I, Section 2 of the MCDL Base OTA No. W15QKN-16-9-1002.

Government Purpose Rights: The rights to (i) use, modify, reproduce, release, perform, display, or disclose Data within the Government without restriction; and (ii) release or disclose Data outside the Government and authorize persons to whom release or disclosure has been made to use, modify, reproduce, release, perform, display, or disclose that Data for Government purposes. Government purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose Data for commercial purposes or authorize others to do so.

In Kind Contribution: This term/condition is not applicable to this Project Agreement, and it is hereby self-deleting from the MCDL Base OTA No. W15QKN-16-9-1002.

Invention: Any invention or discovery which is or may be patentable under Title 35 of the United States Code.

Janssen Consortium: That group of Janssen Consortium Members that are: (i) Affiliates of one another; and (ii) have agreed with one another to collaborate to perform the objectives and obligations set forth in this Project Agreement.

Janssen Consortium Member: Janssen Pharmaceuticals, Inc. ("JPI") acting on behalf of itself and as an agent of JOM Pharmaceutical Services, Inc. ("JOM"), Janssen Research & Development, LLC ("JRD"), Janssen Vaccines & Prevention B.V. ("JV&P"), Janssen Products, LP ("JPLP") and its other affiliates involved in the work under this Project Agreement, propose to come together to form a consortium to work together with the Government. For purposes of this Project Agreement, JPI will act as the contract holder and liaise with the Government as the point of contact for the other Janssen entities. The Consortium Members include each of JPI, JOM, JRD, JV&P, JPLP and their

Affiliates involved in the work under this Project Agreement, and are collectively referred to throughout the proposal as “Janssen.”

Janssen Manufacturing Capability: Janssen’s Manufacturing Capability (“JMC”) is the commercial manufacturing capability that Janssen either owns, operates, manages, leases, rents or contracts with another party at various locations and facilities in order to produce commercial products entirely at private expense for performance of this Project Agreement. The Government has no license in any background intellectual property, background technical data, or other information that is generated to either scale-up or to operate the JMC.

Janssen Prototype Product Rights: All patent, copyright, trade secret, FDA regulatory filings and rights in data within Janssen’s possession and control to sublicense without infringement of third-party intellectual property or agreements, necessary to make, use, offer for sale and sell the Prototype Product within the US market.

Know-How: Information, practical knowledge, techniques, and skill development created by Recipient in performance of the Prototype Project necessary for the Practical Application of a Subject Invention within the Field.

Limited Rights: The rights to use, modify, reproduce, perform, display, or disclose Data or other information, in whole or in part, within the Government solely for research purposes for the Field. The Government will ensure that disclosed information is safeguarded in accordance with the restrictions of this Project Agreement. The Government may not, without the prior written permission of Recipient, release or disclose Data or other information outside the Government, use Data or other information for competitive procurement or manufacture, release or disclose Data or other information for commercial purposes, or authorize Data or other information to be used by another party.

Milestone: Each event identified in the second column of Table 1-1.

Medical CBRN Defense Consortium (“MCDC”): Reference back to Article I, Section 2 of the MCDC Base OTA No. W15QKN-16-9-1002.

MCDC Executive Committee: Reference back to Article I, Section 2 of the MCDC Base OTA No. W15QKN-16-9-1002.

MCDC Members: Reference back to Article I, Section 2 of the MCDC Base OTA No. W15QKN-16-9-1002.

Nontraditional Defense Contractor: Reference back to Article I, Section 2 of the MCDC Base OTA No. W15QKN-16-9-1002.

Other Transaction Agreement (“OTA”): Reference back to Article I, Section 2 of the MCDC Base OTA No. W15QKN-16-9-1002.

Other Transactions for Prototype Projects: Reference back to Article I, Section 2 of the MCDC Base OTA No. W15QKN-16-9-1002.

Party: Each of ATI as the CMF, Janssen, and the Government (collectively, “Parties”).

Payable Milestone: The obligation of the Government, and ATI as the CMF, acting as an agent on the Government’s behalf, to pay Project Agreement Holder/Janssen, in accordance with Article V herein, when Janssen has triggered a payment in accordance with Table 1-1 in Article I, Section 3 of this Project Agreement.

Period of Performance: Contract Award through January 31, 2022.

Practical Application: With respect to a Subject Invention, to manufacture, in the case of a composition of product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions so as to establish that the Subject Invention is capable of being utilized.

Program Manager: This term/condition is not applicable to this Project Agreement, and it is hereby self-deleting from the MCDC Base OTA No. W15QKN-16-9-1002.

Project: Defined in Article III, Section 1 of this Project Agreement.

Project Agreement (“PA”): Refers to this P00081 Modification of the MCDC OTA No. W15QKN-16-9-1002 entered into amongst: Janssen Pharmaceuticals, Inc., on behalf of the Janssen Consortium Members, herein defined; the U.S. Army Contracting Command-New Jersey; and ATI as the MCDC CMF, including the Statement of Work as defined in Article I, Sections 3-6, all attachments and modifications thereto, which are expressly incorporated into and made a part of the Project Agreement. Also referred to as Project Agreement/Statement of Work.

Project Agreement Holder (“PAH”): The MCDC member is Janssen which was issued the Project Agreement by the CMF and ACC-NJ.

Project Management Lead (PML): This is the individual at Janssen responsible for management of this Project.

Prototype Product: At least one of the 100 million Regimens of SARS-CoV-2 vaccine, Ad26.COVS.2 recombinant resulting from the Prototype Project (“Ad26COVS.2”).

Prototype Project: Janssen’s demonstration of its capacity to perform large scale manufacturing domestically, utilizing the Janssen Manufacturing Capability of up to 100 million Regimens of Ad26.COVS.2.

Receiving Party: Reference back to Article VIII, Section 1 of the MCDC Base OTA No. W15QKN-16-9-1002.

Recipient: Janssen Pharmaceuticals, Inc. acting on its own behalf and on behalf of the Janssen Consortium and each Janssen Consortium Member.

Regimen: A “vaccine regimen” or “regimen” is either: two separate injections of 5×10^{10} viral injections (single/low doses/.25ml) or one single injection of 1×10^{11} viral particles (double/high dose/.5ml). If clinical trials support a different dosing or administration regimen, the Parties will discuss how to proceed and may agree to modify this Project Agreement in response.

Subject Invention (“SI”): Any Invention (ii) where the conception of such Invention and either (a) the first actual reduction to practice or (b) constructive reduction to practice of such Invention occurs in performance of the Project.

Subject Invention (“SI”) Intellectual Property Rights: Patent rights controlled by Recipient that are necessary to practice the Subject Invention in the Field.

Technical Direction Letter (“TDL”): This term/condition is not applicable to this Project Agreement, and it is hereby self-deleting from the MDCDC Base OTA No. W15QKN-16-9-1002.

Technology: Discoveries, innovations and Know-How, whether patentable or not, including computer software, recognized under U.S. law as intellectual creations to which rights of ownership accrue, including, but not limited to, patents, trade secrets, and copyrights first created in the Project and that have not been disclosed to the public, but does not include any Subject Invention.

Third-Party Licensee: A US-based entity whose primary business is contract manufacturing for third parties, and is not currently or in the future controlled or affiliated with any entity or business that sells vaccines or pharmaceutical products directly to consumers, pharmacies, health care providers or Governmental entities.

United States Army Contracting Command – New Jersey Contracting Activity (“ACC-NJ”): Reference back to Article I, Section 2 of the MDCDC Base OTA No. W15QKN-16-9-1002.

White Paper: Reference back to Article I, Section 2 of the MDCDC Base OTA No. W15QKN-16-9-1002.

Other capitalized terms used in this Project Agreement, but not defined herein, shall have the meaning set forth in the MDCDC Base OTA No. W15QKN-16-9-1002.

Section I.3 Prototype Project, Milestones, and Pricing Assumptions and Conditions

Prototype Project. The scope of this Prototype Project is the demonstration by Janssen of the rapid, large scale supply and logistics capability to manufacture and deliver to the Government, 100M Regimens of the Ad26.COVS.S vaccine. Consistent with the Government's objectives under Operation Warp Speed ("OWS"), Janssen 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 ("DSCSA") (to the extent required for COVID-19 medical countermeasures, as defined by relevant U.S. Food and Drug Administration ("FDA") guidance), to manufacture and deliver the Ad26.COVS.S vaccine. The successful provision of these Regimens shall establish the effectiveness of a technology capable of potentially providing immediate and long-term solutions to coronavirus infections. While preclinical and clinical activities are described in the Introduction section of this Statement of Work, the Parties acknowledge and agree that such activities are not related to the large-scale manufacturing demonstration and are out-of-scope for this Prototype Project.

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 Janssen 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 regimens required for vaccination of the U.S. population. Successful completion of the Prototype Project will demonstrate Janssen's capability to rapidly manufacture product, which can be further scaled-up to meet mutually agreed to surge requirements with limited advance notification.

Milestones/Payments. One hundred million Regimens of Ad26.COVS.S vaccine will be provided by Janssen to the Government on a Firm Fixed Price ("FFP") per Regimen basis in accordance with the Milestone Payment Schedule. Due to variances in fill/finish yield, Janssen shall invoice for and the Government, through the CMF, shall pay for actual quantities delivered, at a rate of \$10.00 per Regimen. Janssen shall use its reasonably diligent efforts to provide the Government the full 100M Regimens on or before the final delivery date. The Government will be under no obligation to receive or pay for any Regimens that are not made available for delivery according to the schedule defined in Table 1-1, except that (a) deliveries will be considered to be timely made according to the schedule to the extent that they are made up to 30 calendar days after the applicable delivery date, due to delays related to manufacturing, testing, or release, and (b) the Government will be obligated to accept and pay for Regimens that are not timely delivered by an initially applicable delivery date or within the alternative delivery windows identified in this paragraph, to the extent that any delay in delivery is solely attributable to an Excusable Delay Event as defined in Article IX, Section 4 of this Project Agreement. The Government will, at its discretion, have unilateral authority to extend future delivery dates before they have passed to the extent that any of the 100M Regimens are not expected to be delivered according to the schedule defined in Table 1-1; however, Janssen will be under no obligation to deliver Regimens after December 31, 2021, unless mutually agreed to by both Janssen and the Government. For the avoidance of doubt, to the extent there is a shortfall in the amount of Regimens delivered by any given delivery date, which is not

excused or extended by the terms of this paragraph, then Janssen shall be free to dispose of such shortfall in its sole discretion.

Janssen's current production plan contemplates 100% of release of finished Regimens in 2020 and January and February of 2021 will occur in the US. If Janssen changes this plan in any substantial way, it will discuss with the Government adjustments to this Project Agreement that are consistent with the principles established in this section.

On a month-by-month basis, for any Regimen that Janssen manufactures and releases in the United States in excess of the number of Regimens that Janssen planned to release in the United States for delivery under this Project Agreement from January through June 2021 (irrespective of the source of drug substance), the Government will have an option: (i) for the months of January and February 2021, to purchase 100 percent of such excess; and (ii) for all remaining months, to purchase 20 percent of such excess Regimens at a price of, in each case, \$10/Regimen and agrees that Janssen may allocate or sell the remaining amount of such excess at Janssen's sole discretion. For each delivery month identified in Table 1-1, Janssen will notify the Government about any such excess Regimens on or before the 15th of that month, and the Government will have 5 working days after receiving such notice in which to exercise its option. If the Government exercises its option, Janssen will provide the ordered excess Regimens by the delivery date identified in Table 1-1 for the month in which Janssen provided its notice. Any excess Regimens that are delivered in a particular month will be subtracted from the number of Regimens that Janssen would otherwise be required to deliver in the last month of scheduled deliveries as reflected in Table 1-1. In the event that, as the result of the purchase of excess Regimens as contemplated under this paragraph, no delivery is due in the last month of scheduled deliveries as reflected in Table 1-1, any excess Regimens that are delivered in a particular month will be subtracted from the number of Regimens that Janssen would be required to deliver in what would then be the final month in which deliveries under this Project Agreement will take place. Notwithstanding the foregoing, the Government's option may not be exercised in a way that would require Janssen to deliver more than 100 million Regimens under this Project Agreement.

In the event that Janssen is able to commence delivery of Regimens manufactured and released in the United States prior to January of 2021, the Government shall have a right of first refusal to purchase such Regimens as set forth in this Paragraph. The Government's right shall cover hundred (100) percent of such Regimens. Janssen will notify the Government about the availability of such Regimens within fifteen (15) calendar days after learning of their availability. The Government will then have five (5) working days after receiving such notice in which to exercise its right of first refusal. Janssen may allocate or sell any Regimens that the Government does not elect to purchase in its sole discretion. Any purchased Regimens shall be subtracted from the quantity of Regimens Janssen is required to deliver in the last month of scheduled deliveries as reflected in Table 1-1. In the event that any such subtraction results in Janssen being required to deliver no Regimens in the last month of deliveries as reflected in Table 1-1, any additional or subsequent early deliveries will be subtracted from what would then be the final month in which deliveries under this Project Agreement will take place.

Notwithstanding the foregoing, the Government's rights may not be exercised in such a way that would require Janssen to deliver more than 100 million Regimens under this Project Agreement.

Janssen is currently pursuing external validation of its not-for-profit calculation approach for the pricing of its Regimens to ensure it meets its commitment to make the Regimens available on a not-for-profit basis for use in the emergency pandemic, and Janssen is developing a framework under which any profit would be returned to purchasers of the Regimens. The Parties agree that the Government will benefit from the application of these procedures. This Project Agreement will not be closed out until at least one external validation is complete such that an appropriate credit can be completed if the final not-for-profit price per Regimen is determined to be less than \$10. In no case shall the price per Regimen exceed \$10.

Table 1-1: Milestone Payment Schedule

Milestone Number	Milestone Description	Delivery Date	Value
1	2M Regimens of Ad26.COV2.S	On or before 1/31/2021	\$20,000,000
2	10M Regimens of Ad26.COV2.S	On or before 2/28/2021	\$100,000,000
3	25M Regimens of Ad26.COV2.S	On or before 3/31/2021	\$250,000,000
4	25M Regimens of Ad26.COV2.S	On or before 4/30/2021	\$250,000,000
5	25M Regimens of Ad26.COV2.S	On or before 5/31/2021	\$250,000,000
6	13M Regimens of Ad26.COV2.S	On or before 6/30/2021	\$130,000,000
7	Long-term Storage of Drug Product (Option)	(b) (4), (b) (2)	\$1,650,000
Total (FFP)			\$1,001,650,000
Date of Final Delivery			6/30/2021

Pricing Assumptions and Conditions

- 1) Short-term storage not to exceed 30 days and delivery to no more than 10 sites in the continental United States, are included in the \$10/Regimen pricing.
- 2) At the discretion of the Government, Janssen shall provide the Government with up to twelve (12) months storage of up to 100M Regimens of Ad26.COV2.S (Milestone Number 7), (b) (4), (b) (2).
 The Government shall pay Janssen the full FFP amount, as identified in Table 1-1, distributed evenly across each month ordered for long-term storage capacity, with payment for each month due at the end of the applicable month. As applicable, Janssen will invoice the Government less per month for storage to the extent necessary to reflect Janssen storage vendor charges that are lower than expected for each month.

Section I.4 Scope of P00081 Modification

Subject to Article I, Section 1, the following efforts are included in the scope of this Project Agreement/Statement of Work:

Current Good Manufacturing Practice (“cGMP”) manufacturing, fully compliant with 21 CFR 210 and 211 subject to any guidance from, enforcement discretion exercised by, or formal waiver issued by the FDA in connection with COVID-19, of 100M Regimens of Ad26.COVS.2 for distribution by the Government upon EUA under Section 564 of the Food, Drug, and Cosmetics (“FD&C”) Act or a biologics licensure granted under Section 351(a) of the Public Health Service (“PHS”) Act by the FDA, including:

- Final DP vaccine presentation will be subject to evaluation and discussion with the appropriate regulatory authorities under the BARDA OTA No. HHSO001201700018C. As such, the Parties understand and agree that the vaccine presentation may change during performance.
- Labeling of EUA Regimens using the date of manufacture, and not expiry, in order to ensure continuous supply of Ad26.COVS.2, recombinant vaccine is maintained and not disrupted when FDA licensure is received.
- Storage of up to 100 million Regimens of Ad26.COVS.2 at Janssen or vendor facility.
- Compliance with the DSCSA Sections 581-585 of PL 113-54 (Nov 27, 2013), including product verification, serialization (serialization requirements need to be further evaluated and may impact timelines for delivery), traceability and detection and response requirements, unless exempted under DSCSA or other applicable legal exception, subject to any guidance from, enforcement discretion exercised by, or formal waiver issued by the FDA in connection with COVID-19.
- Shipping, if required, to up to ten (10) USG directed destinations.
- In coordination with the Government, Janssen will conduct a demonstration of the vaccine shipping process prior to the first delivery of doses at a time mutually agreed to by the Parties. Janssen 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.

Section I.5 Prototype Deliverables

Table 1-5: Prototype Deliverables

Deliverable Number	Deliverable Description	Due Date	Format	Data Rights
1	Project Kickoff Materials	Within 30 calendar days after award	Agenda, PPT Slides, etc.	Government Purpose Rights
2	Phase 2/3 Clinical Trial Synopsis	Within 7 calendar days after FDA approval	Janssen-determined format	Government Purpose Rights
3	Provision of PL 115-92 (optional)	10/31/2020	n/a	As Described in Agreed upon Letter
4	Weekly Production Updates / Regimen Tracker	Weekly, upon award	Template to be provided by USG	Government Purpose Rights
5	Monthly Business and High-Level Technical Report	On or before the 15 th of each month	Janssen-determined format	Government Purpose Rights
6	EUA Filing	Within 7 calendar days after submission to FDA	Janssen-determined format	Limited Rights***
7	BLA Filing	Within 7 calendar days after submission to FDA	Janssen-determined format	Limited Rights***
8	Delivery of 100M Regimens	According to Table 1-1	n/a	n/a
9	Release documentation for delivered Regimens	According to Table 1-1	Janssen-determined format	Government Purpose Rights
10	Supply Chain Resiliency Plan or Janssen Equivalent	Within 30 calendar days after award	Janssen-determined format	Government Purpose Rights
11	Manufacturing Data Requirement or Janssen Equivalent	Within 30 calendar days after award	Janssen-determined format	Government Purpose Rights
12	Product Development Source Material	Within 30 calendar days after award	Janssen-determined format	Government Purpose Rights
13	Work Location Report or Janssen Equivalent	Within 30 calendar days after award	Janssen-determined format	Government Purpose Rights
14	Facility Security Plan or Janssen Equivalent	Within 30 calendar days after award	Janssen-determined format	Government Purpose Rights
15	Confirmation of Registration and Listing with FDA	Within 7 calendar days of receipt	Janssen-determined format	Government Purpose Rights
16	Formal Written Responses from the FDA	Within 7 calendar days of receipt	n/a	Government Purpose Rights
17	FDA Inspection and Compliance Notices, Observations and Responses	Within 7 calendar days of receipt	n/a	Government Purpose Rights

18	Manufacturing Development Plan*	Within 7 calendar days of completion	Janssen-determined format	Limited Rights***
19	Quality Management Plan**	Within 7 calendar days of completion	Janssen-determined format	Limited Rights***
20	Shipping Specifications and Details	Within 7 calendar days of completion	Janssen-determined format	Government Purpose Rights

* Manufacturing Development Plan. Janssen will, in the level of detail and format that Janssen solely elects (*provided* such format provides a reasonable and industry-standard level of detail), 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 GMP. This plan shall describe as such information becomes available to Janssen, but is not limited to, planned or completed drug substance studies; list of excipients and information to support the safety of excipients that, when appropriate, shall be cross-referenced; drug product and formulation development summary from initial concept through final design; physicochemical and biological properties; manufacturing process development and validation program documents; container closure system documents; microbiological attributes documents and plans; compatibility documents (*e.g.*, precipitation); assay development and validation, stability plan; and any associated risks.

** Quality Management Plan. Janssen will, in the level of detail and format that Janssen solely elects (*provided* such format provides a reasonable and industry-standard level of detail), provide a quality management plan which may include, but is not limited to, the quality policy and objectives, management review, competencies and training, process document control, feedback, evaluation, corrective action and preventive action, process improvement, measurement, and data analysis processes. The framework is normally divided into infrastructure, senior management responsibility, resource management, lifecycle management, and quality management system evaluation.

*** Both parties agree that in addition to USG funding for advanced research and development of Janssen's potentially viable vaccine for COVID-19, Janssen independently invested significantly more over a course of decades to develop the platform technology and capability. Accordingly, in recognition of the disproportionate levels of investment, the government accepts limited rights to use certain data that was predominantly developed at Janssen's expense.

All Deliverables intended for the Agreements Officer's Representative ("AOR") shall be delivered.

At least one copy of all data Deliverables shall be sent to: usarmy.detrick.dod-jpeo-cbrnd.mbx.otadeliverable@mail.mil.

Section I.6 Follow-on Production

This Project Agreement/Statement of Work hereby is eligible for the award of a follow-on production contract for Ad26.COV2.S subject to the requirements of 10 U.S.C. § 2371b (f)(2)(A) and (B) and (f)(3). In accordance with 10 U.S.C. § 2371b(f), and upon successful demonstration of the Prototype Project or at the accomplishment of particularly favorable or unexpected results that would justify transitioning to production (e.g., EUA or BLA), additional production of up to 200M Regimens, may be awarded to partially or completely meet the USG objective of supplying a safe and effective Ad26.COV2.S to the entire US population. This Project Agreement includes options that are priced at Janssen's global not-for-profit price of \$10/Regimen as described in Article I, Section 3 above, for follow-on production, not to exceed 200 million Regimens. During the performance of the Project Agreement, the Government and Janssen will finalize the scope of production. If the Prototype Project is successful, as described in this Article I, Section 6, the Government may then enter into follow-on production by executing these options through a separate stand-alone production agreement.

Article II. Term and Termination

Section II.1 Term

The Period of Performance for this Project Agreement/Statement of Work is from the date of contract award through January 31, 2022.

Section II.2 Termination

Termination for Vaccine Discontinuation. In the event that (a) Janssen notifies the Government that, as a result of significant emerging safety or efficacy data, Janssen is ceasing efforts to develop the Ad26.COV2.S, or (b) such a vaccine receives U.S. regulatory approval or authorization on or prior to expiration of the period of performance of this Project Agreement, but such approval or authorization is subsequently withdrawn and, after a reasonable amount of time, the Government determines that the authorization will not be restored or approval will not be granted, the Government will notify Janssen of its intent to terminate this Agreement. Under (a), if Janssen notifies the Government in good faith of a significant safety or efficacy issue, and the Government does not respond within a reasonable amount of time, then Janssen has the right to terminate the Project Agreement.

Janssen shall have no liability to repay the Government for Regimens delivered prior to the notification of termination. Janssen shall be entitled to full payment for Regimens for which manufacturing has been completed, but which have not yet been delivered to the Government. With respect to Regimens for which manufacturing has been initiated but not completed, Janssen shall be entitled to payment of a proportion of the \$10/Regimen price based on a percentage of the work performed toward release and delivery of such Regimens, plus reasonable charges that Janssen can demonstrate to the satisfaction of the Government using its standard record keeping system to have resulted from the

termination, but not to exceed \$10/Regimen. By way of example, these costs may include, but are not necessarily limited to, costs associated with non-cancellable agreements with vendors to obtain manufacturing capacity or supplies in the performance of this Project Agreement. Janssen shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit Janssen's records. Janssen shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

From and after the effective date of any such termination, Janssen shall have no further obligation to deliver any vaccine Regimens, and the Government shall have no further obligation to accept any such Regimens for delivery. After termination of this Project Agreement, Janssen may sell or transfer to a third party any Regimens that have not been delivered to the Government.

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.

Section II.3 Extension of Term

The Parties may extend by mutual written agreement the term of this Project Agreement if funding availability and research opportunities reasonably warrant. Any extension shall be formalized through modification of the Project Agreement by the Agreements Officer ("AO") and the Janssen Project Manager ("PM"). If the Recipient desires an extension to the period of performance of this Project Agreement, the Recipient shall submit a request in writing to the AO. Any request for an extension should include a revised milestone/project schedule (if applicable).

Article III. Project Management, Modifications, and Administration

Section III.1 Management and Modifications

Technical and project management of the manufacture and delivery of up to 100 million Regimens of Ad26.COV2.S ("Project") and the anticipated follow-on activities described in Article I, Section 6 above, established under this Project Agreement, shall be managed as detailed in this Article.

- a. **Project Governance.** Janssen is responsible for the overall management of the Prototype Project and related decisions. The Government and Janssen are bound to each other by a duty of good faith in achieving the Prototype Project objectives as defined in Article I. As such, the Government will have continuous involvement with Janssen. Janssen shall provide project results in accordance with the Deliverables schedule identified in Article I.
- b. **Project Management.** Janssen and the Government will each designate an individual responsible for facilitating the communications, reporting, and

meetings between the Parties. For Janssen the individual will serve as PM, and for the Government the individual will be the AOR.

- c. **Project Reviews.** Janssen and the Government will hold periodic project review meetings as determined by the Janssen Project Manager and AOR, however, these meetings shall not occur more frequently than every fourteen (14) calendar days.
- d. **Reviews Resulting in Modifications.** During the performance of this Project Agreement, as described above, it may be necessary to modify the Statement of Work or delivery timeframes. No communications, whether oral or in writing, that purport to change this Project Agreement are valid unless a modification is issued by the AO. The Parties hereby agree that any mutually agreed upon written request for modification shall be executed in an expedited timeframe.
- e. **Bilateral Modifications.** Janssen or the Government may propose modifications to this Project Agreement. A modification that materially changes the obligations of either the Government or Janssen must be in writing and signed by the AO and Janssen's authorized official. Janssen's requests for modifications shall detail the technical and chronological impact of the proposed change on the Statement of Work or delivery timeframes.
- f. **Unilateral Modifications.** The AO may ONLY issue minor or administrative modifications, which do not change the obligations of Janssen in any adverse manner, such as changes to the paying office or appropriations data, or changes to Government personnel identified in the Project Agreement. Unilateral modifications will only be signed by the AO.

Section III.2 Project Agreement Administration

Government Points of Contact:

AO

NAME: (b) (6)
MAILING ADDRESS: Phipps Rd, Picatinny Arsenal, NJ 07806-5000
EMAIL: (b) (6)
PHONE: (b) (6)
AGENCY NAME/DIVISION/SECTION: CCONJ-ET

AOR

NAME: (b) (6)
EMAIL: (b) (6)
PHONE: (b) (6)
AGENCY NAME/DIVISION/SECTION: HHS/ASPR/BARDA

Janssen Points of Contact:**CLM**

NAME:
MAILING ADDRESS:
EMAIL:
PHONE:

(will be provided within 30 calendar days after award)

PM

NAME:
MAILING ADDRESS:
EMAIL:
PHONE:

(will be provided within 30 calendar days after award)

ATI:

Advanced Technology International
MCDC Contracts
315 Sigma Drive
Summerville, SC 29486

Article IV. “PREP ACT” Coverage

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 Health and Human Service’s (“HHS”) Declaration Under the Public Readiness and 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 Project 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) Janssen’s performance of this Project 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) Janssen 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 Project Agreement, as long as Janssen’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 Project Agreement, unless such use occurs in the United States (or a U.S. territory where U.S. law applies such as embassies, military installations and NATO installations) 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. Any use where the application of the PREP Act is in question will be discussed with Janssen prior to use and, if the parties disagree on such use, the dispute will be resolved according to Article VI, “Disputes.”

If the Government agrees to provide any additional clarity about the applicability of PREP Act immunity to any maker of a vaccine or pharmaceutical product to prevent or treat SARS-CoV-2, COVID-19, or mutations therefrom, the Government will provide the same clarity to Janssen under this Project Agreement.

Article V. Obligation and Payment

Section V.1 Limitation of Liability

In no case shall the Parties’ financial liability for performance exceed the amount obligated under this Project Agreement/Statement of Work.

Section V.2 Fixed Price Payment Method

Payments shall be made in accordance with the payment schedule of this Project Agreement/Statement of Work, as shown in Article I, Section 3 above, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. An acceptable invoice for FFP payments is one that (on the invoice):

- a. contains the date of invoice and the base Agreement number and Project Agreement number;
- b. identifies any associated technical milestones and the progress toward completion of each milestone; and
- c. lists the price contained in each Project Agreement.

Section V.3 Accounting System Requirements

Prior to the submission of invoices, Janssen shall have and maintain an established accounting system which complies with Generally Accepted Accounting Principles ("GAAP") and the requirements of this Project Agreement. Consistent with this stipulation, an acceptable accounting system will be one in which all cash receipts and disbursements are controlled and documented properly.

Section V.4 Payments and Payment Instructions

- a. The Parties agree that fixed payments will be made for delivery of product or storage. These payments reflect the value received by the Government toward the accomplishment of the goals of this Project Agreement.
- b. Janssen shall submit an original invoice as described in Article V, Section 2, above, via (b) (4) Payment terms are NET 30 days after CMF's receipt of an invoice that meets the conditions of Article V, Section 2 above.
- c. In accordance with Article XII, herein, the Government shall inspect, accept or reject the work as promptly as practicable after submission or completion, unless otherwise specified in this Project Agreement/Statement of Work. Government failure to inspect, accept or reject the work shall not relieve Janssen from responsibility, nor impose liability on the Government, for nonconforming work. Work is nonconforming when it is defective in material or workmanship or is otherwise not in conformity with contract requirements. The remedy for nonconforming is rework by Janssen within reasonably revised timelines.
- d. The Parties hereby agree that reasonable delays in performance of this Project Agreement/Statement of Work shall not be considered nonconforming work, as defined above. The Parties hereby further agree that Janssen has provided timelines based on its best estimates in accordance with the Government's accelerated timeframes and that the nature of vaccine production/manufacturing is inherently complex and in order to ensure appropriate quality, safety and efficacy standards are met, some delays are unavoidable and these delays will be addressed by the Parties under the Governance structure of Article III of this Project Agreement/Statement of Work, as the circumstances dictate at that time. Each delivery identified in Table 1-1 will be made independent of the other deliveries, and a failure to make one or more deliveries will not impact the Parties' obligations with respect to the other deliveries as long as Janssen continues to make reasonably diligent efforts to make each delivery under this Project Agreement.

Section V.5 Comptroller General Access to Records

To the extent that the total Government payment under this Project Agreement exceeds \$5,000,000, the Comptroller General, at its discretion, shall have access to and the right to examine records relevant to the work hereunder of any Consortium Member participating in the performance of this Project Agreement for a period of three (3) years after final payment is made. This requirement shall not apply with respect to any Consortium Member that participates in the performance of the Project Agreement that has not entered into any other Project Agreement (contract, grant, cooperative agreement, or “other transaction”) that provides for access by a Government entity in the year prior to the date of this Project Agreement. This paragraph only applies to any record that was created or maintained in the ordinary course of business or pursuant to a provision of law in the performance of the Project Agreement.

Article VI. Disputes

A. General

The Parties shall communicate with one another in good faith and in a timely, responsive, and cooperative manner when raising issues under this Article.

B. Dispute Resolution Procedures

1. Any claim or dispute between the Government and Janssen concerning questions of fact or law arising from or in connection with this Project Agreement, and, whether or not involving an alleged breach of this Project Agreement, shall be raised and resolved under this Article.
2. Whenever legal disputes or claims arise, the Parties shall attempt to resolve the issue(s) by discussion and come to mutual agreement on a resolution as soon as practicable. In no event shall a dispute, disagreement or misunderstanding that arose more than three (3) months prior to the notification made under sub-section B.3 of this article constitute the basis for relief under this article unless one level above the AO, in the interests of justice, waives this requirement.
3. Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party (through the AO or Janssen’s POC, as the case may be) in writing of the relevant facts, identifying unresolved issues, and specifying the clarification or remedy sought. Within five (5) working days after providing notice to the other Party, the aggrieved Party may, in writing, request a joint decision by the ACC-NJ Division Chief for Emerging Technologies and senior executive appointed by Janssen. The other Party shall submit a written response on the matter(s) in dispute within thirty (30) calendar days after being notified that a decision has been requested. The Division Chief and the Recipient

senior executive shall conduct a review of the matter(s) in dispute and attempt to render a mutually agreeable decision in writing within thirty (30) calendar days of receipt of such written position. Any such joint decision is final and binding.

4. In the absence of a joint decision, upon written request to the ACC-NJ Associate Director made within thirty (30) calendar days of the expiration of the time for a decision under sub-section B.3 above, the dispute shall be further reviewed. The Associate Director may elect to conduct this review personally or through a designee or jointly with a senior executive appointed by Janssen. Following the review, the Associate Director or designee will resolve the issue(s) and notify the Parties in writing. This decision may be appealed to any federal court of competent jurisdiction.
5. Notwithstanding any other provisions of this Article, the Parties agree that Janssen shall have the right to pursue any contract dispute arising under this Project Agreement in any federal court of competent jurisdiction, including the appropriate Court of Appeals, or the Supreme Court, at any time without any administrative exhaustion requirements, and the timing requirements described above will not limit any claim in such tribunals. For the avoidance of doubt, the Parties agree that this Project Agreement satisfies all elements of an agreement.

C. Limitation of Damages

Claims for damages of any nature whatsoever pursued under this Project Agreement shall be limited to direct damages only up to the aggregate amount of Government funding obligated as of the time the dispute arises, except with respect to violations of the confidentiality, data rights, intellectual property, or PREP Act provisions of this Project Agreement.

Article VII. Confidential Information

Section VII.1 Authorized Disclosure

The Receiving Party shall not directly or indirectly, divulge or reveal to any person or entity any Confidential Information of another Party without the Disclosing Party's prior written consent, or use such Confidential Information except as permitted under this Project Agreement. Confidential Information shall be subject to the same prohibitions on disclosure as provided for under FAR Part 24.202. Further, any reproduction of Confidential Information or portions thereof that is disseminated within the Government, CMF, or Janssen, shall be shared strictly on a need to know basis for the purposes of this Project Agreement and is subject to the restrictions of this provision. In addition to the above, Confidential Information is subject to the protections of the Trade Secrets Act as well as any other remedies available under this Project Agreement or the law.

Section VII.2 Exclusions

Such obligation of confidentiality shall not apply to information which the Receiving Party can demonstrate through competent evidence: (i) was at the time of disclosure in the public domain; (ii) has come into the public domain after disclosure through no breach of this contract; (iii) was known to the Receiving Party prior to disclosure thereof by the Disclosing Party; (iv) was lawfully disclosed to the Receiving Party by a Third Party which was not under an obligation of confidence to the Disclosing Party with respect thereto; or (v) was approved for public release by prior written permission of the Disclosing Party.

Section VII.3 Term

The obligations of the Receiving Party under this Article shall continue for a period of seven (7) years from conveyance of the Confidential Information.

Article VIII. Publication and Academic Rights

Section VIII.1 Use of Information.

Janssen shall have the right to publish or otherwise disclose information and/or data generated under the Project. Janssen shall include an appropriate acknowledgement of the funding of the Project by the Government in any publication. Notwithstanding the above, the Parties shall not be deemed authorized by this paragraph, alone, to disclose any Confidential Information of another Party to this Project Agreement.

Section VIII.2 Publication or Public Disclosure of Data

Review and Approval of Data for Public Release.

(1) At least 30 days prior to the scheduled release date, Janssen shall submit to the AOR a copy of the Data to be released.

(2) An acknowledgment similar to the following shall be required in any publication of any Data, based or developed under this Project Agreement:

“Effort funded in part by the U.S. Government under P00081 Modification to Other Transaction Number W15QKN-16-9-1002 between the Janssen Pharmaceuticals, Inc., MCDC, and the Government.”

(3) Parties to this Project Agreement are also responsible for assuring that every publication of material funded under this project contains the following disclaimer:

“The views and conclusions contained herein are those of the authors and do not be represent the official policies or endorsements, either expressed or implied, of the U.S. Government.”

Article IX. Patent Rights

Section IX.1 Background Intellectual Property Disclosures

Janssen asserts full title to all background intellectual property relevant to its performance of this statement of work and listed at Attachment 1. Janssen hereby conveys a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States to the "Licensed Patents" throughout the world for the prevention, diagnosis and treatment of COVID-19 caused by Severe Respiratory Syndrome-Coronavirus-2 (SARS CoV-2). "Licensed Patents" means US Provisional Patent Application Serial Nos. (b) (4)

as well as any and all patent applications and patents (including any counterparts, PCT's, national stage applications, divisionals, continuations, or the like thereof, and any extensions thereof), wherever filed in the world, that claim priority to US Patent Application Serial No. (b) (4)

The Parties agree that nothing in this Project Agreement will otherwise alter the existing patent rights of the Parties unless expressly agreed upon.

Section IX.2 Allocation of Principle Rights

If Janssen elects to retain title to a Subject Invention, Janssen or its designee shall retain the entire right, title, and interest throughout the world to each Subject Invention developed under this Project Agreement consistent with the provisions of this Article and 35 U.S.C § 202 subject to the retention by the Government of a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States any Subject Invention. The license retained by the Government does not include the right to use or allow others to use the Subject Invention for commercial purposes.

Section IX.3 Invention Disclosure, Election of Title, and Filing of Patent Application

- a. Janssen shall disclose each Subject Invention to the Government within two (2) months of the Subject Invention being disclosed in writing to the person responsible for Janssen patent matters. The Subject Invention shall be disclosed in writing to the Government, via appropriate filings in the iEdison system or its replacement/alternative system, with a copy of said reporting being sent to JPEO-CBRND. Further, Janssen shall elect in writing whether or not to retain title to any such invention by notifying the Government within 6 months of disclosure to the Government.
- b. Where publication, sale, or public use has initiated the one (1)-year statutory period wherein valid patent protection can still be obtained in the United States,

the period for such notice of election may be shortened by the Government to a date that is no more than sixty (60) calendar days prior to the end of the statutory period.

- c. If electing title, Janssen will file its initial patent application on a Subject Invention to which it elects to retain title within one year after election of title, or, if earlier, prior to the end of the statutory period wherein valid patent protection can be obtained in the United States after a publication, or sale, or public use.
- d. Foreign Patent Filing Requirements: Janssen may elect to file corresponding patent applications in additional countries outside the U.S. (including but not limited to the European Patent Office and the Patent Cooperation Treaty) at its discretion. To enable the Government to protect patent rights in Subject Inventions in all potential countries, Janssen shall inform the Government of which countries Janssen shall NOT file patents applications in for all elected Subject Inventions at least 3 months prior to the filing deadline therein (e.g., in PCT national stage applications, at least 3 months prior to the PCT national stage filing deadline). Janssen understands that, in case the Government decides to file in a particular country following a notice provided under the preceding sentence, all ownership and interest in Subject Inventions in said countries (where Janssen shall not file patent applications in) are thereby automatically conveyed to the Government, and Janssen agrees to timely execute any documentation required to effectuate this conveyance, so as to enable the Government to perfect patent filing in said countries, always subject to the license described in Article IX, Section 5(a).
- e. If Janssen does not elect title via the process described above, or determines that neither it nor its designee intends to file any patent applications on a Subject Invention, Janssen shall notify the Government, in writing, within 6 months of disclosure of such Subject Invention to the Government. Janssen agrees, in such case, to permit the Government to elect title to said Subject Invention, and thereby have full rights and ownership therein, at least 3 months PRIOR to the end of the one (1)-year statutory period wherein valid patent protection can still be obtained in the United States after any publication, sale, or public use.
- f. In addition to the reporting required above, Janssen shall identify Subject Inventions in an annual report and the final report, which shall be in sufficiently complete technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the Subject Invention.
- g. Neither Party will publicly disclose any Subject Invention until a patent application describing the Subject Invention is filed, or a reasonable period of time has passed in the event that a patent application is not filed, in order to protect the patentability of the invention pursuant to 35 U.S.C. § 205.

Section IX.4 Conditions When the Government May Obtain Title

Upon JPEO-CBRND's written request, Janssen shall convey title to the Government:

- a. Of any Subject Invention, if Janssen fails to disclose the Subject Invention or elects not to retain title to the Subject Invention within the times specified in Article IX, Section 3(a) and (b), the Government may request title for a period of up to 60 calendar days after learning of the failure of Janssen to disclose within the specified times. For the avoidance of doubt, disclosure under this paragraph shall be deemed to have occurred at the time of Janssen's notification to JPEO-CBRND of a Subject Invention regardless of whether such disclosure meets the standards set forth in Article IX, Section 3(a) above.
- b. Of a patent application or patent that claims a Subject Invention, as the case may be, in any country in which Janssen decides not to continue the prosecution of such patent application, or to pay the maintenance fees on or defend in reexamination or opposition proceedings such a patent.

Section IX.5 Minimum Rights to Janssen's Consortium and Protection of Janssen's Consortium's Right to File.

- a. Janssen shall retain a nonexclusive, royalty-free license throughout the world in each Subject Invention to which JPEO-CBRND obtains title under Article IX, Section 8. The Janssen license extends to the Janssen's Affiliates, and includes the right to grant licenses of the same scope to the extent that Janssen was legally obligated to do so at the time the Project Agreement was awarded or at the time of the Subject Invention was invented. The license is transferable only with the approval of JPEO-CBRND, except when transferred to the successor of that part of the business to which the Subject Invention pertains. JPEO-CBRND approval for license transfer shall not be unreasonably withheld.
- b. The Janssen license may be revoked or modified by the Government to the extent necessary to achieve expeditious Practical Application of the Subject Invention pursuant to an application for an exclusive or non-exclusive license submitted consistent with appropriate provisions at 37 CFR Part 404.
- c. Before modification of the license, JPEO-CBRND shall furnish Janssen a written notice of its intention to revoke or modify the license, and Janssen shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be modified.

Section IX.6 Action to Protect JPEO-CBRND's Interest

- a. Janssen agrees to execute or to have executed and promptly deliver to JPEO-CBRND all instruments necessary to (i) establish or confirm the rights JPEO-CBRND has throughout the world in those Subject Inventions to which Janssen elects to retain title, and (ii) convey title to JPEO-CBRND when requested under Section 4 of this Article IX and to enable JPEO-CBRND to obtain patent protection throughout the world in that Subject Invention.
- b. Janssen agrees to require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing, to personnel identified as responsible for the administration of patent matters and in a format suggested by Janssen, each Subject Invention in order that Janssen can comply with the disclosure provisions of Section 3 of this Article IX. Janssen shall instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting Subject Inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.
- c. Janssen shall notify JPEO-CBRND of any decisions not to continue the prosecution of a patent application claiming a Subject Invention, pay maintenance fees on a patent claiming a Subject Invention, or defend in a reexamination or opposition proceedings on a patent claiming a Subject Invention, in any country, not less than sixty (60) calendar days before the expiration of the response period required by the relevant patent office.
- d. Janssen shall include, within the specification of any United States patent application and any patent issuing thereon claiming a Subject Invention, the following statement: "This invention was made with Government support under Agreement [W15QKN-19-6-1002, 2011-004], awarded by JPEO-CBRND. JPEO-CBRND has certain rights in the invention."

Section IX.7 Reporting on Utilization of Subject Inventions

- a. Janssen shall submit, during the term of the Project Agreement, an annual report on the utilization of Subject Inventions or on efforts at obtaining such utilization that are being made by or on behalf of Janssen or its licensees or assignees. Such reports will include information regarding the status of development, date of first commercial sale or use, and such other data and information as the agency may reasonably specify. Janssen shall provide additional reports as may be requested by JPEO-CBRND in connection with any march-in proceedings undertaken by the Government in accordance with Article IX, Section 8 of this Project Agreement. Consistent with 35 U.S.C. § 202(c) (5), JPEO-CBRND agrees it shall not disclose such information to persons outside JPEO-CBRND without permission of Janssen.

- b. All required reporting shall be submitted to the AO and AOR.
- c. Where the Subject Invention is a drug or a vaccine, or a method of manufacturing, administering or using a drug or vaccine, Practical Application in view of the March-in Rights in Article IX, Section 8 below is achieved with respect to:
 - i. such drug or vaccine, if a Phase IIa clinical study is completed that studies such drug or vaccine; or
 - ii. such method of use, if the method of use is employed in manufacture, administration or use of such drug or vaccine in connection with a Phase IIa clinical study.
- d. Failure to complete a Phase IIa clinical study does not per se constitute a failure to achieve Practical Application.

Section IX.8 March-in Rights

Janssen agrees that, with respect to any Subject Invention in which it has acquired title, the Government may request Janssen, an assignee, or exclusive licensee of a Subject Invention to grant a non-exclusive license, within the Field of use to a responsible US-based third party, upon terms that are reasonable under the circumstances. If Janssen, assignee, or exclusive licensee initially refuses such a request, the Government may obligate Janssen to grant such a license subject to Article IX, Section 8(c) below if the Government determines that:

- a. Such action is necessary because Janssen or assignee has not taken steps (or is not expected to take within a reasonable time), consistent with the intent of this Project Agreement, to achieve Practical Application of the Subject Invention; or
- b. Such action is necessary to alleviate the following urgent health or safety needs not reasonably satisfied by the contractor that affect the United States and that are not reasonably satisfied by Janssen, assignee, or their licensees:
 - i. declaration for Public Health Emergency by the Secretary of the Government;
 - ii. determination that there is a significant potential for a public Health emergency that has a significant potential to affect the national security or public health of U.S. citizens as determined by the Secretary of the Government; or
 - iii. declaration by WHO Director General of a public health emergency of

international concern.

- c. Where the circumstances described in Article IX, Section 8(a) and or (b) are met, Janssen will act promptly to negotiate in good faith with the responsible US-based third party a non-exclusive license on terms that are reasonable under the circumstances under the SI Intellectual Property Rights it controls at the time to make, have made, use, sell, offer for sale and import the relevant Subject Invention in the Field to the extent necessary to alleviate the public health emergency in the United States.

Section IX.9 Background Information

Janssen shall retain the entire right, title, and interest throughout the world to each such Invention and Patent that Janssen has brought to the Prototype Project issued under this Project Agreement/Statement of Work and the Government shall not have any rights under this Project Agreement/Statement of Work to such Inventions and Patents unless identified herein. Attachment 1 to the Project Agreement contains non-exhaustive overview of Janssen's Background Patents, patent applications and Inventions at the Effective Date. Table 10-1 in Article X "Data Rights" provides a non-exhaustive overview of Data Rights, information and Technical Data that Janssen will bring to the Project Agreement at the Effective Date. The Government shall have no rights to these Background Inventions, Patents, information and Technical Data and any further Background Inventions, Patents, information and Technical Data identified during the Term of the Project Agreement or afterwards.

Article X. Data Rights

Table 10-1: Janssen Background Information, Data Rights and Technical Data

<i>Technical Data to be Furnished with Restrictions</i>	<i>Basis for Assertion</i>	<i>Asserted Rights Category</i>	<i>Name of Person Asserting Restrictions</i>
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen

Technical Data to be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Person Asserting Restrictions
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen

Section X.1 Data Categories

Article XI of the Agreement, is hereby superseded by the following terms and conditions:

There are two (2) categories of Data or other information established under this Project Agreement as listed below.

- a. Category A is Data or other information to which Janssen retains all rights. Category A Data shall include, but not be limited to:
 - i. Data as defined in the Project Agreement, background (i.e., pre-existing or generated outside the scope of this Project Agreement) information and Technical Data identified in Table 10-1 and Attachment 1 (background Patents, patent applications and Inventions), and any designs or other material provided by Janssen for this Project Agreement which was not developed in the performance of work under this project, and to which Janssen retains rights.
 - ii. The Parties hereby mutually agree that any information developed outside of this Project Agreement whether or not developed with any Government funding in whole or in part under a Government agreement, contract or subcontract shall have the rights negotiated under such prior agreement, contract or subcontract; the Government shall get no additional rights in such information.
- b. Category B is any Data developed exclusively with Government funds under this Project Agreement.
 - i. The Government will have Government Purpose Rights in Data developed exclusively with Government funds under this Project Agreement.
 - ii. The Government shall have unlimited rights in Data:
 - (a) Otherwise publicly available or that has been released or disclosed by Janssen without restrictions on further use, release or disclosure, other than a release or disclosure resulting from the sale, transfer, or other assignment of interest in the Data to another party or the sale or transfer of some or all of a business entity or its assets to another party;
 - (b) Data in which the Government has obtained unlimited rights under another Government contract or as a result of negotiations; or
 - (c) Data furnished to the Government, under this or any other

Government contract or subcontract thereunder, with—

1. government purpose rights or limited rights and the restrictive condition(s) has/have expired; or
 2. Government purpose rights and Janssen's exclusive right to use such Data for commercial purposes under such contract or subcontract has expired.
- iii. However, any Data or other information developed outside of this OTA whether or not developed with any Government funding in whole or in part under a Government agreement, contract or subcontract shall have the rights negotiated under such prior agreement, contract or subcontract; the Government shall get no additional rights in such Data or other information.

Section X.2 Allocation of Principle Rights

- a. The Government shall have no rights to Category A Data or other information, but shall have rights to Deliverables as described in Table I-5.
- b. The Government will receive Government Purpose Rights in Data or other information exclusively funded by the Government and otherwise Limited Rights in any data delivered in the performance of the SOW. To the extent that the Parties mutually agree that there will be Data subject to Government Purpose Rights, Data subject to Government Purpose Rights may only be shared with parties outside the Government when such parties are subject to the non-disclosure agreement at DFARS 227.7103-7 with respect to the data or are receiving the data under a Government contract subject to DFARS 252.227-7025. Any delivered Data or other information which is part of a patent application claiming a Subject Invention will be subject to the disclosure and release restrictions set forth in Article X, Section 2 of this Project Agreement.
- c. Data or other information in any document which is a part of a patent application that would disclose a Subject Invention will be subject to Limited Rights until publication of patent application in accordance with Article X of this Project Agreement/Statement of Work.
- d. Janssen agrees to retain and maintain in good condition all Data necessary to achieve Practical Application of any Subject Invention in accordance with the Janssen's established record retention practices. In the event of exercise of the Government's March-in Rights as set forth under Article X, Janssen agrees, upon written request and with adequate additional support from the Government, as mutually agreed between the Parties, to deliver Data necessary to achieve Practical Application within one-hundred and twenty (120) calendar days from the date of the written request.

- e. Janssen's right to use Data is not restricted and includes the right under Janssen's established business policies to make public research data (especially human research data) by publication in the scientific literature, by making trial protocols, trial results summaries, and clinical studies reports publicly available, and by making trial patient-level data available for third-party analysis. The Government agrees that the materials, if any, being developed under this Project Agreement/Statement of Work are being developed for both civilian and military applications.

Section X.3 Identification and Disposition of Data

Janssen shall keep copies of all Data required by the FDA relevant to this Project Agreement for the time specified by the FDA and provide such Data to AO. The Government reserves the right to review any other Data determined by the Government to be relevant to this Project Agreement/Statement of Work subject to Limited Rights.

a. Marking of Data

Pursuant to section A above, any Data delivered under this Project Agreement/Statement of Work that is subject to Government Purpose Rights shall be marked with the following legend or similar:

"GOVERNMENT PURPOSE RIGHTS: The Government's right to use, modify, reproduce, perform, display or disclose this Data is restricted by P00081 Modification to the MCDC OTA No. W15QKN-16-9-1002 between the Government, ATI and Janssen, and those restrictions do not permit disclosure to any party outside the Government unless such disclosure is for government purposes and not facilitating commercial sale beyond the government. Any reproduction of this Data or portions thereof must be marked with this legend."

- b. Pursuant to section A above, any Data delivered under this Project Agreement/Statement of Work that is subject to Limited Rights shall be marked with the following legend or similar:

"LIMITED RIGHTS: The Government's right to use, modify, reproduce, perform, display or disclose this Data is restricted by P00081 Modification to the MCDC OTA No. W15QKN-16-9-1002 between the Government, ATI and Janssen, and those restrictions do not permit disclosure to any party outside the Government without prior agreement of Recipient. Any reproduction of this Data or portions thereof must be marked with this legend."

Article XI. Export Control

This term/condition is not applicable to this Project Agreement.

Article XII. Government Furnished Property

It is not anticipated that any Government furnished equipment, materials, information, or other property will be provided to Janssen nor will Janssen procure any property intended to be Government furnished under this Project Agreement.

Article XIII. Civil Rights Act

Reference back to Article XIV of the MCDL Base OTA No. W15QKN-16-9-1002.

Article XIV. Small Business Affiliation

This term/condition is not applicable to this Project Agreement.

Article XV. Antitrust

This term/condition is not applicable to this Project Agreement.

Article XVI. Security and Operations Security (“OPSEC”)

To the extent that Janssen does not meet any requirements in this Article XVI or Attachment 2 at the time of award of this Project Agreement, Janssen will notify the Government and will have 180 days to work with the Government to develop a plan to which Parties agree to address such requirements, Janssen will be entitled to an equitable adjustment to account for costs associated with implementing the plan agreed to by the Parties.

The OPSEC provisions included in Attachment 2 are hereby incorporated into this Project Agreement.

All PAH shall comply with DFARS 252.204-7012 (Oct 2016): Safeguarding Covered Defense Information and Cyber Incident Reporting when applicable.

Covered Defense Information (“CDI”) will be identified at the Project Agreement level. The MCDL Member shall comply with DFARS 252.204-7012 (Oct 2016): Safeguarding Covered Defense Information and Cyber Incident Reporting, which includes implementing on its covered contractor information systems the security requirements specified by DFARS 252.204-7012. Nothing in this paragraph shall be interpreted to foreclose the MCDL Member's right to seek alternate means of complying with the security requirements in National Institute of Standards and Technology (“NIST”) Special Publication (SP) 800-171 (as contemplated in DFARS 252.204-7008 (Compliance with

Safeguarding Covered Defense Information Controls) (Oct 2016) and DFARS 252.204-7012 (Safeguarding Covered Defense Information and Cyber Incident Reporting (Oct 2016)).

(1) For all Project Agreements, the following statement shall be flowed to the MCDC member entities unless otherwise stated within the Project Agreements.

a) Classification guidance for requirement - "The security level for this agreement is UNCLASSIFIED."

Article XVII. Safety

This term/condition is not applicable to this Project Agreement.

Article XVIII. Representations and Warranties

Reference back to Article XIX of the MCDC Base OTA No. W15QKN-16-9-1002.

Section XVIII.1 Representations and Warranties of All Parties

Each Party to this Project Agreement represents and warrants to the other Parties that (1) it is free to enter into this Agreement; (2) in so doing, it will not violate any other agreement to which it is a party; and (3) it has taken all action necessary to authorize the execution and delivery of this Project Agreement and the performance of its obligations under this Project Agreement.

Section XVIII.2 Limitations

Except as expressly provided herein, no Party to this Project Agreement makes any warranty, express or implied, either in fact or by operation of law, by statute or otherwise, relating to (1) any research conducted under this Project Agreement, or (2) any invention conceived and/or reduced to practice under this Project Agreement, or (3) any other intellectual property developed under this Project Agreement or noninfringement, and EACH PARTY TO THIS PROJECT AGREEMENT SPECIFICALLY DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY OR WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.

Article XIX. General Provisions

Section XIX.1 Fees

This term/condition is Not Applicable to this Project.

Section XIX.2 Waiver

Reference back to Article XXI, Section 2 of the MDCDC Base OTA No. W15QKN-16-9-1002.

Section XIX.3 Section Headings

Reference back to Article XXI, Section 3 of the MDCDC Base OTA No. W15QKN-16-9-1002.

Section XIX.4 Severability

If any provision of this Project Agreement, or the application of any such provision to any person or set of circumstances, is determined to be invalid, unlawful, void or unenforceable to any extent, the remainder of this Project Agreement, and the application of such provision to persons or circumstances other than those as to which it is determined to be invalid, unlawful, void or unenforceable, will not be impaired or otherwise affected and will continue to be valid and enforceable to the fullest extent permitted by law.

Section XIX.5 Excusable Delay

Neither Party will be liable to the other Party for failure or delay in performing its obligations hereunder if such failure or delay arises from circumstances beyond the control and without the fault or negligence of the Party (an "Excusable Delay Event"). Examples of such circumstances are: authorized acts of the Government in its sovereign capacity (or failure to take reasonably expected acts), war, insurrection, freight embargos, fire, flood, or strikes. The Party asserting Excusable Delay as an excuse must take reasonable steps to minimize delay or damages caused by unforeseeable events. The Government may not identify any aspect of the COVID-19 pandemic as an Excusable Delay Event relieving it of its responsibilities under this Project Agreement.

Section XIX.6 Regulatory Rights

- a. The Parties understand and hereby acknowledge that BARDA OTA No. HHSO100201700018C ("BARDA OTA") governs Janssen's responsibilities and obligations with regards to IND activities regarding Janssen's Ad26.COVS vaccine, specifically, Work Package 6.14, "Regulatory Support" of the BARDA OTA. Under the BARDA OTA, Janssen leads regulatory activities with the FDA. Janssen manages all regulatory communications, documentation, and submissions with health authorities. Janssen provides BARDA with all communications and summaries thereof, both formal and informal, to or from FDA regarding the Investigational New Drug ("IND") activities regarding Janssen's Ad26.COVS vaccine and will invite the BARDA/JPEO-CBRND representatives to participate in any formal meetings between FDA and Janssen. Additionally, for this Project Agreement, Janssen will authorize BARDA to share information with the United States Department of Defense, JPEO-CBRND, as BARDA deems appropriate, in accordance with the Data Rights requirements of BARDA OTA No. HHSO100201700018C.
- b. The Parties also understand that PL-115-92 allows the DoD to request, and FDA to provide, assistance to expedite development and the FDA's review of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. Janssen recognizes that only the DoD is authorized to invoke PL-115-92. If Janssen, the DoD, and BARDA agree that the circumstances exist under the BARDA OTA to warrant DoD's involvement, Janssen and BARDA may request DoD to utilize its authority under PL-115-92 to engage the FDA.

If DoD, in its sole discretion, determines that it will engage with the FDA, the Parties agree that DoD will only invoke this authority in order to assist or facilitate Janssen in obtaining the necessary FDA approvals or authorizations. Notwithstanding any other provision in this Project Agreement, the BARDA OTA, or PL-115-92, the Parties agree that DoD shall not use its authority to become a "sponsor," co-sponsor, or "applicant" as defined in the regulations cited in this Article. Further, the Parties hereby agree that any information provided to DoD by Janssen, to facilitate with the FDA under PL-115-92, will be provided with Limited Rights pursuant to the BARDA OTA.

- c. *Rights of Reference.* In the event that all of the conditions described in Article 19, Section 7(1) are met, Janssen will grant the Government a right of reference to any regulatory application submitted to the FDA in support of this Project Agreement/Statement of Work. Separately, upon the DoD's request, Janssen will grant the DoD a right of reference to any regulatory application submitted to the FDA in support of this Project Agreement/Statement of Work for the DoD's regulatory filings involving (a) the use of a product to treat or prevent COVID-19 or (b) one of the material threats identified in Attachment 3, in each case for which the DoD is identified as the filing sponsor. DoD may request a

right of reference to additional material threats identified by the Government under Section 319F-2(c)(2)(A)(ii) of the Public Health Service Act, and Janssen may consent to provide such a right of reference with the agreement that its consent will not be unreasonably withheld. For clarity, the rights of reference identified in this paragraph will only authorize the FDA to cross-reference regulatory applications and will not provide the DoD or any other party with a right to access or review any such applications or information included in such applications.

Section XIX.7 Failure to Provide Prototype Product

1. In recognition of the Government's need to provide sufficient quantities of a safe and effective Prototype Product to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the Prototype Product to meet the needs of the public health or national security when the following conditions are met:

- a. Janssen gives written notice (which it hereby agrees to do) to the Government no later than 15 business days following:
 - i. except as permitted under Article I, Section 3 or in connection with a termination of this Project Agreement under Article II, Section 2 above, any formal management decision to terminate manufacturing of the Prototype Product prior to delivery of 100 million Regimens of the Prototype Product to USG; or
 - ii. except as permitted under Article I, Section 3 or in connection with a termination of this Project Agreement under Article II, Section 2 above, any formal management decision to discontinue sale of the Prototype Product to the Government prior to delivery of 100 million Regimens of the Prototype Product to USG; or
 - iii. any filing that anticipates Federal bankruptcy protection of Janssen prior to the delivery of 100 million Regimens of the Prototype Product; and
- b. Janssen
 - i. is authorized to supply the Prototype Product under an Emergency Use Authorization under §564 of the FD&C Act; or
 - ii. has an FDA approval to market the Prototype Product in the U.S. under the provisions of §351(a) of the Public Health Service Act (PHSA).

2. If both conditions listed in subsection (1) occur, Janssen, during the emergency pandemic for COVID-19 issued under §319 of the PHSA, upon the written request of the Government, will act promptly to license a Third-Party Licensee all Janssen Prototype Product Rights on reasonable terms for the continuation and/or initiation of manufacturing of the Prototype Project at the Government's expense.

3. This Article will survive the acquisition or merger of Janssen with a third party. This Article will survive the expiration of this Project Agreement unless the Project Agreement was terminated under Article II, Section 2(a).

Section XIX.8 Radioactive Materials

This term/condition is not applicable to this Project Agreement.

Section XIX.9 Recombinant DNA

This term/condition is not applicable to this Project Agreement.

Section XIX.10 Required Compliance for Use of Laboratory Animals

This term/condition is not applicable to this Project Agreement.

Section XIX.11 Required Compliance for Use of Human Subjects

This term/condition is not applicable to this Project Agreement.

Section XIX.12 Required Compliance for use of Human Anatomical Substances

This term/condition is not applicable to this Project Agreement.

Section XIX.13 Compliance with Good Manufacturing Processes

The cGMP (21 CFR 210-211) will be the standard applied for manufacturing, processing and packing of any products to be administered to human subjects under this Project Agreement subject to any applicable guidance from, or enforcement discretion exercised by, the FDA in connection with COVID-19 subject to any applicable guidance from, or enforcement discretion exercised by, the FDA in connection with COVID-19.

If at any time during the life of this contract, the Recipient fails to comply with cGMP in the manufacturing, processing and packaging of the products subject to the exception noted above and such failure results in a material adverse effect on the safety, purity or potency of the products (a material failure) as identified by Center for Biologics Evaluation and Research and Center for Drug Evaluation and Research, the Recipient shall have thirty (30) calendar days from the time such

material failure is identified to cure such material failure. If the Recipient fails to take such an action within the thirty (30) calendar day period, then the contract may be terminated.

The Recipient agrees to comply with cGMP guidelines (21 CFR Parts 210-211,600) for manufacturing, processing and packing of drugs, chemicals, biological, and reagents subject to any applicable guidance from, or enforcement discretion exercised by, the FDA in connection with COVID-19.

The Recipient agrees to advise the AO and AOR promptly of any relocation of their prime manufacturing facility or the relocation of any sub consortium's facility during the term of this Project Agreement. The Recipient also agrees to advise the AO and AOR immediately if at any time during the term of this Project Agreement, the items under this OTA fail to comply with cGMP guidelines and/or the facility receives a negative FDA Quality Assurance Evaluation (Form 483).

Section XIX.14 Registration with Select Agent Program

This term/condition is not applicable to this Project Agreement.

Section XIX.15 Duty Free Entry

Reference back to Article XXI, Section 14 of the MCDC Base OTA No. W15QKN-16-9-1002.

Article XX. Assignment of Agency

Neither this Project Agreement nor any rights or obligations of any Party hereunder shall be assigned or otherwise transferred by any Party without the prior written consent of the other Parties, except that Janssen may assign to an Affiliate or to a third party to whom it transfers the portion of its business applicable to this Project Agreement, in each case, without prior written consent.

Article XXI. Order of Precedence

In the event of any inconsistency between the general terms of this Project Agreement and the Agreement, the inconsistency shall be resolved by giving precedence in the following order: (1) the Scope/Statement of Work of the Project Agreement; (2) Attachments to the Project Agreement; (3) the Project Agreement terms and conditions; (4) documentation (including but not limited to Janssen's proposal selected for funding by the Government); (5) the general terms and conditions of the Agreement. In any event, specifically negotiated Project Agreement terms will govern over general terms of the Agreement.

The Parties mutually agree that any terms and conditions that have been identified with the following statement **"This term/condition is Not Applicable to this Project**

Agreement” shall have no effect and are expressly excluded from the MCDC Base OTA No. W15QKN-16-9-1002. The terms and conditions in the MCDC Base OTA No. W15QKN-16-9-1002, that have been changed within this Project Agreement, are hereby superseded by the language in this Project Agreement. As such, those sections from the MCDC Base OTA No. W15QKN-16-9-1002 shall no longer remain operative with regards to this Project Agreement/Statement of Work. Any terms and conditions that have not been changed or have not been identified with the above statement remain unchanged and in full force and effect.

Article XXII. Execution

This Project Agreement constitutes the entire agreement of the Parties and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions among the Parties, whether oral or written, with respect to the subject matter hereof. This Project Agreement may be revised only by written consent of Janssen and the AO. This Project Agreement, or modifications thereto, may be executed in counterparts each of which shall be deemed as original, but all of which taken together shall constitute one and the same instrument.

Article XXIII. Antibribery and Anti-Corruption

The Government acknowledges that it has received and read Recipient's 'Prevention of Corruption - Third Party Guidelines.' Each Party agrees to perform its obligations under this Project Agreement in accordance with the applicable anti-bribery and anti-corruption laws of the territory in which such Party conducts business with the other Party as set forth herein. Each Party shall be entitled to exercise its termination right, under and in accordance with the terms of this Project Agreement, to terminate this Project Agreement immediately on written notice to the other Party, if the other Party fails to perform its material obligations in accordance with this Article XXIII.

Article XXIV. Inspection, Acceptance, & Delivery

A. Acceptance

- Upon acceptance by the AOR of any lot of vaccine under this Project Agreement and confirmation from the AO, title to such vaccine will transfer upon (a) delivery of DP to vendor-managed inventory (“VMI”), or delivery to a site designated by the Government, as initially applicable, and (b) the Government’s corresponding written acceptance of each delivery. Storage as VMI may only take place up to twelve months after (b) (4), (b) (2) [REDACTED]
[REDACTED]
[REDACTED]
- Any deviations, out of specification (“OOS”) results, or other product issues, shall be reported to the USG within 3 calendar days after initial delivery.

- When held in VMI, these materials should be maintained in Janssen's or its designated representative's quality and inventory systems. Delivered Regimens are intended for clinical use or use under Emergency Use Authorization or a BLA. Product held in VMI is subject to the following requirements:
 - Provide temperature controlled storage at the manufacturer's site approved by the Government, according to cGMP and product specifications.
 - Store Project Agreement products physically segregated from other products.
 - Ensure proper labeling of stored materials as USG property.
 - Execute stability testing of stored material in a manner consistent with the stability testing plan approved by the Government. Report interim data and results to the Government on a monthly basis.
 - Appropriately identify reserve samples that are representative of drug product shall be retained. The reserve samples consist of at least twice the quantity necessary for all tests required to determine whether the drug product meets its established specifications including a minimum of 60 months of stability testing.
 - Provide the Government access to review the security systems in place and request updates as needed.
 - Include in monthly report inventory for drug product (number of vials), including inventory quantity changes, current quantity, storage facility/location, manufacturing date, latest stability result for potency, date of next expected stability result and the current expiration date (if applicable).
 - Ensure that material being relocated for Janssen's convenience is adequately insured at no cost to the government and with AO approval.
 - Conduct testing necessary to ensure continued use of the stored material for pandemic response.
 - Make appropriate updates to the regulatory documentation supporting the continued use of the stored material for pandemic response.
 - If using a storage site, provide the quality agreement, specify the location and terms of the storage contract and receive approval by the Government.

- Notification must be made to the AO and AOR at least 10 calendar days prior to initial delivery. Exceptions are permitted if approved by the AO.
- The Government shall accept product that conforms to contract requirements based on Certificates of Analysis and certificate(s) of cGMP conformity provided by Janssen. The Government's acceptance of product will be deemed to have occurred if the Government does not provide written notice of acceptance or rejection within fourteen (14) calendar days of Janssen's provision of all applicable certificates.
- Upon receipt of the provided certificates and any inspection that was timely requested (physical or representative, i.e., pictures), the AOR will review and recommend acceptance or rejection; the AO will correspondingly notify Janssen of acceptance or rejection.
- Upon delivery of product, notification of delivery quantities and any movement must be made to the AOR and Government representatives.
- Upon request before storage in VMI or, if storage was initially ordered, after storage in VMI, unless otherwise mutually agreed upon by the Parties, DP shall be shipped, trackable by GPS, to the Government-designated sites within the continental United States.
- Janssen will retain physical risk of loss for all product stored as VMI until subsequent delivery to the Government at the Government-designated site. If product is initially delivered to a Government site instead of VMI, risk of loss will transfer upon delivery and acceptance at the Government-designated site. Notwithstanding either of the foregoing sentences, Janssen shall not be liable for loss of or damage to supplies caused by the negligence of officers, agents, or employees of the Government acting within the scope of their employment.
- Janssen will notify the AO and AOR of any storage or quality deviation for product held in VMI, within 3 calendar days.
- To the extent that Janssen is responsible for the correction, repair or replacement of Government property held in VMI and replacement upon loss or damage is feasible, the Government will accept replacement of such property.
- Vendor-managed storage of product manufactured under this Project Agreement is supported for up to twelve months after (b) (4), (b) (2) and, as such, the Government must either (a) take possession on or before the end of this period and provide Janssen with disposition instructions in sufficient time to transfer physical material from Janssen by this date or (b) bilaterally modify

this Project Agreement to extend the period of vendor management of storage prior to this date.

- The Government understands that prices identified in this contract include insurance costs applicable to material that will become Government property, including product stored as VMI.
- Janssen cannot reclaim title to product upon acceptance by the Government. Prior to expiration or termination of this Project Agreement, the Government may affect final distribution of any vaccines remaining in storage by any one or combination of the following methods:
 - The Government may elect to require shipment of the vaccine to US Government facilities.
 - The Government may direct Janssen to destroy all quantities remaining in storage. In this case, a letter of disposition will be provided to the USG.

B. Inspection

USG right to inspect product: The AO and/or the AOR may perform inspection of materials and services. Inspections of material created under this Project Agreement may be made by a duly authorized Government representative, and with reasonable notice (i.e., not less than 24 hours).

Article XXV. Foreign Access to Technology

(a) Except as authorized by the Office of Foreign Assets Control ("OFAC") in the Department of the Treasury, the Contractor shall not acquire, for use in the performance of this contract, any supplies or services if any proclamation, Executive order, or statute administered by OFAC, or if OFAC's implementing regulations at 31 CFR chapter V, would prohibit such a transaction by a person subject to the jurisdiction of the United States.

(b) Except as authorized by OFAC, most transactions involving Cuba, Iran, and Sudan are prohibited, as are most imports from Burma or North Korea, into the United States or its outlying areas. Lists of entities and individuals subject to economic sanctions are included in OFAC's List of Specially Designated Nationals and Blocked Persons at <http://www.treas.gov/offices/enforcement/ofac/sdn/>. More information about these restrictions, as well as updates, is available in the OFAC's regulations at 31 CFR chapter V and/or on OFAC's website at <http://www.treas.gov/offices/enforcement/ofac>.

(c) The Contractor shall insert this clause, including this paragraph (c), in all subcontracts.

Article XXVI. Government Observer in Recipient Facility

With seven (7) days advance notice to the Recipient in writing from the AO, the Government may place an observer in a Recipient facility that is being used for work hereunder, who shall be subject to Recipient's policies and procedures regarding security and facility access at all times while in the Recipient's facility and who shall limit its activities to observing work related to this Project Agreement. As determined by federal law and as required under this Project Agreement/Statement of Work, no Government representative shall publish, divulge, disclose or make known in any manner, or to any extent not authorized by law, any information disclosed to that person in the course of employment or official duties performed while stationed in a Recipient facility.

Article XXVII. Reporting Matters Involving Fraud, Waste and Abuse

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in ASPR funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll-free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhs.gov and the mailing address is:

Office of Inspector General
Department of
Health and Human
Services TIPS
HOTLINE
P.O. Box 23489
Washington, D.C. 20026

Article XXVIII. Prohibition on Contractor Involvement with Terrorist Activities

The Recipient acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O.13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Recipient to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this Project Agreement.

Article XXIX. Survival

Articles IV (PREP Act); V (Payment); VI, Sections (B) & (C) (Disputes and Limitations on Damages); VII (Confidential Information), IX (Patent Rights), X (Data Rights) and this Article XXIX shall survive the termination provisions in Article II, Section 2.

Section XXIX.1 Close-out Procedure

If the Government funds an individual Project Agreement and then subsequently terminates the agreement or the requirements of the Project Agreement are met, the following closeout procedures apply:

(a) Definitions.

- (i) “Closeout” – the process by which the Government and CMF determine that all applicable administrative actions and all required work have been completed by Janssen.
- (ii) “Date of Completion” – the date on which all work is completed or the date on an amendment thereto on which the period of performance ends.

(b) Upon request, the Government shall make prompt payments to Janssen through the CMF for outstanding payments and reimbursements under the Project Agreement being closed out.

(c) Janssen shall immediately refund any balance of unobligated (unencumbered) cash that the CMF has paid and that is not authorized to be retained by Janssen for use in the performance of the Project Agreement.

(d) The CMF shall obtain from Janssen within 180 calendar days after the date of completion of an Project Agreement all financial, performance, and other reports required as a condition of the Project Agreement. The CMF may grant extensions when requested by Janssen.

(e) Reserved.

(f) Quick close-out procedures similar to FAR 42.708 shall be followed.

(g) Janssen shall account for any property received from the Government.

ATTACHMENT 1:**Janssen's Background Patents, Patent Applications and Inventions****Listed Janssen Background Intellectual Property and Technical Data**

Attachment 1 comprises a table with the full list of pending and granted patents in the patent families listed below that, to the best of Janssen's knowledge, is accurate as of July 9, 2020. Janssen makes no representations or warranties with regards to the accuracy or completeness of that information. The Parties mutually agree that Janssen is not obligated to maintain the currency or accuracy of the information provided in the table.

Certain patent applications / patents on this list are registered at the patent office with Crucell Holland B.V. as the applicant. Crucell Holland B.V. was acquired by Johnson & Johnson in 2011 and subsequently changed its name to Janssen Vaccines & Prevention in 2016.

Certain patents on this list are owned by (b) (4) Janssen holds a license to these patents.

COVID Vaccination and Dosage Regimen:

Janssen has filed patent application(s), or is the assignee or licensee of pending patent applications including those listed below which contain(s) claims that are related to COVID Vaccines and Dosage regimens

- All patent applications and/or resulting patents (including any foreign counterparts, divisionals, continuations, or the like thereof, and any extensions thereof) that include a priority claim to (b) (4)

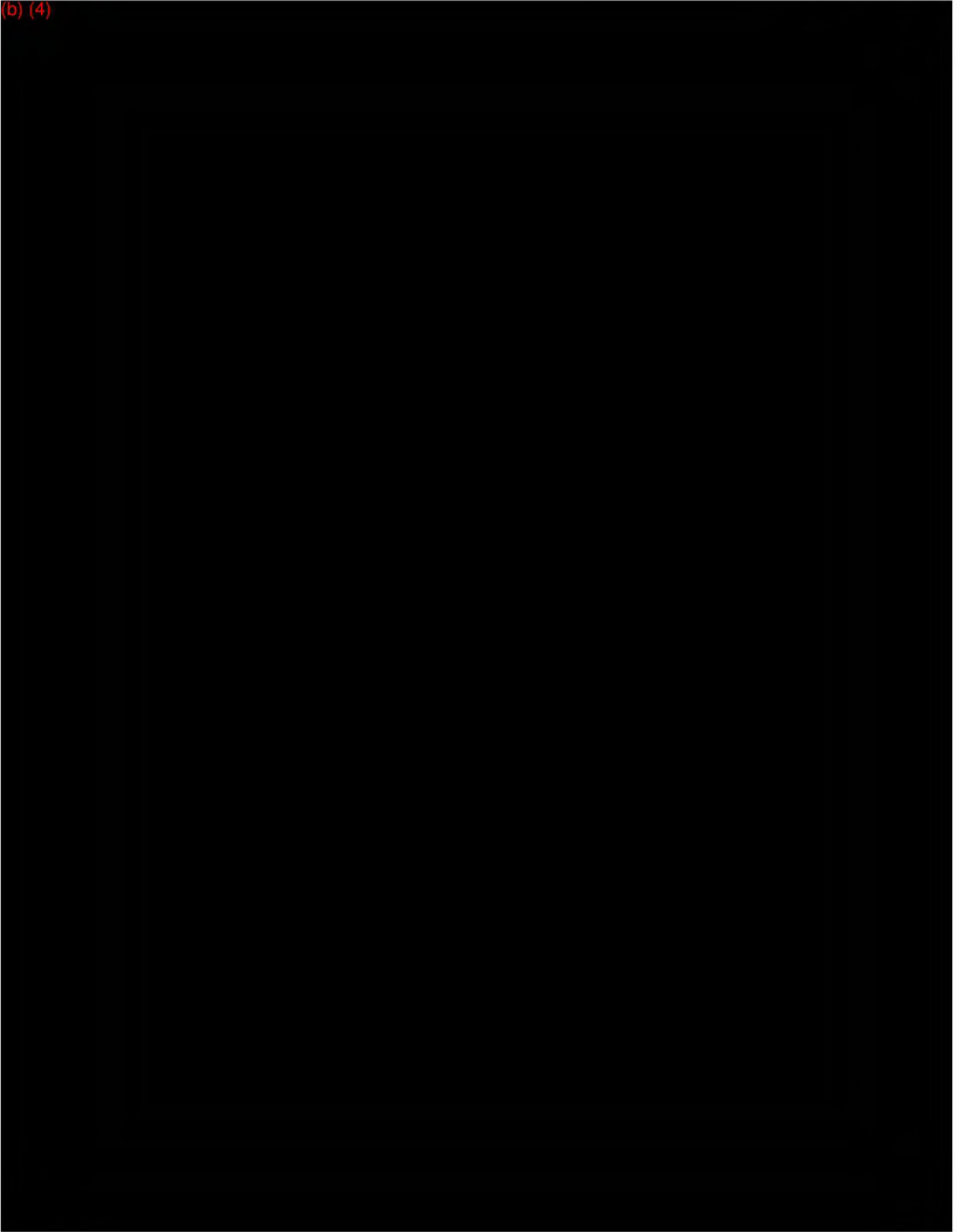
PER.C6® Technology and/or AdVac® Technology:

Janssen has filed patent application(s), or is the assignee or licensee of pending patent applications and/or issued patent(s), including those listed below which contain(s) claims that are related to PER.C6® technology and/or AdVac® technology.

(b) (4)



(b) (4)



(b) (4)

Table X: Janssen Assertion of Data Rights Technical Data

Technical Data to be Furnished With Restrictions	Basis for Assertion	Asserted Rights Category	Name of Person Asserting Restrictions
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen

Technical Data to be Furnished With Restrictions	Basis for Assertion	Asserted Rights Category	Name of Person Asserting Restrictions
(b) (4) [REDACTED]	[REDACTED]	A	Janssen
(b) (4) [REDACTED]	[REDACTED]	A	Janssen
(b) (4) [REDACTED]	[REDACTED]	A	Janssen

Table: List of pending and granted background patents as of July 9, 2020.

[illegible]

[illegible]

[illegible]

(b) (4)

AMERICAN
OVERSIGHT

[illegible]

[illegible]

[illegible]

(b) (4)

[illegible]

[illegible]

[illegible]

(b) (4)

[illegible]

(b) (4)

[illegible]

[illegible]

(b) (4)

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

(b) (4)

Government	Percentage
Current government	95%
Previous government	5%

ATTACHMENT 2:

Additional OPSEC Requirements

ATTACHMENT 3:**Material Threats**Biological Threats

- 1 Bacillus anthracis (anthrax) and Multi-drug resistant B. anthracis (MDR anthrax)
- 2 Burkholderia mallei (glanders) and Burkholderia pseudomallei (melioidosis)
- 3 Clostridium botulinum toxin (botulism)
- 4 Ebola virus (Ebola hemorrhagic fever)
- 5 Francisella tularensis (tularemia)
- 6 Marburg virus (Marburg hemorrhagic fever)
- 7 Pandemic influenza
- 8 Rickettsia prowazekii (typhus)
- 9 Variola virus (smallpox)
- 10 Yersinia pestis (plague)

Chemical Threats

- A. Acetylcholinesterase inhibitor nerve agents
- B. Chlorine
- C. Cyanide salts (potassium and sodium cyanide)
- D. Hydrogen cyanide
- E. Phosgene
- F. Vesicants

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0058

The CLIN extended description has changed from:

PLACE HOLDER - RPP 20-11 Objective 20-11 is being authorized under CLIN 0058 for “Janssen’s COVID-19 Vaccine – Large Scale Domestic Production.” The total approved cost by the Government for this effort is not to exceed \$1,010,000,000.00. The total amount authorized to Janssen is \$1,001,650,000.00. The total amount authorized to ATI is \$8,350,000.00 (broken out as \$8,350,000.00 Cost and \$0.00 Fixed Fee).

To:

RPP 20-11 Objective 20-11 is being awarded under CLIN 0058 for “Janssen’s COVID-19 Vaccine – Large Scale Domestic Production.” The total approved cost by the Government for this effort is not to exceed \$1,010,000,000.00. The total amount awarded to Janssen is

\$1,001,650,000.00. The total amount authorized to ATI is \$8,350,000.00 (broken out as \$8,350,000.00 Cost and \$0.00 Fixed Fee).

SUBCLIN 005802 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
005802	Funding for CLIN 0058 CPFF Funding is being added to CLIN 0058 in the amount of \$999,999,999.99. The total amount awarded to Janssen is \$999,999,999.99. The total amount awarded to ATI is \$0.00 (broken out as \$0.00 Cost and \$0.00 Fixed Fee). PURCHASE REQUEST NUMBER: 0011532810				\$0.00
				ESTIMATED COST	\$0.00
				FIXED FEE	\$0.00
					\$0.00
				TOTAL EST COST + FEE	
	ACRN GT				\$999,999,999.99
	CIN: GFEB001153281000001				

SUBCLIN 005803 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
005803	Funding for CLIN 0058 CPFF Funding is being added to CLIN 0058 in the amount of \$1,650,000.01. The total amount awarded to Janssen is \$1,650,000.01. The total amount awarded to ATI is \$0.00 (broken out as \$0.00 Cost and \$0.00 Fixed Fee). PURCHASE REQUEST NUMBER: 0011532810				\$0.00
				ESTIMATED COST	\$0.00
				FIXED FEE	\$0.00
					\$0.00
				TOTAL EST COST + FEE	
	ACRN GU				\$1,650,000.01
	CIN: GFEB001153281000002				

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 005802:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The following Acceptance/Inspection Schedule was added for SUBCLIN 005803:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by \$1,001,650,000.00 from \$6,328,970,669.79 to \$7,330,620,669.79.

SUBCLIN 005802:

Funding on SUBCLIN 005802 is initiated as follows:

ACRN: GT

CIN: GFEB001153281000001

Acctng Data: 0212020202120400000664643255 S.0074658.5.14 6100.9000021001

Increase: \$999,999,999.99

Total: \$999,999,999.99

Cost Code: A5XAH

SUBCLIN 005803:

Funding on SUBCLIN 005803 is initiated as follows:

ACRN: GU

CIN: GFEB001153281000002

Acctng Data: 0212020202120400000664643255 S.0074658.5.14.1 6100.9000021001

Increase: \$1,650,000.01

Total: \$1,650,000.01

Cost Code: A5XAH

(End of Summary of Changes)