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

REPLY TO
ATTENTION OF

18 December 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 Definitized "Adjuvanted Recombinant COVID-19 Vaccine Development" Sanofi Pasteur, Inc. (Sanofi)

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

Dear (b) (6),

The Army Contracting Command – New Jersey (CCNJ), 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. On 30 July the Government awarded a combination Cost/Firm-Fixed Price Undefinitized Project Agreement (UPA) and later modified that award to adjust the Consortium Management Firm (CMF) Administrative Fee. The total obligation for this project is $1,769,343,470 ($1,769,013,470 to perform project efforts included in the SOW and $330,000 for the CMF Administrative Fee).

On, 10 September Sanofi submitted a proposal in response to the Government's Request for Prototype Proposal (RPP) 20-11. The Government reviewed the proposal and determined that the proposed amount of $1,769,343,470 is appropriate for the work to be to be performed in accordance with the attached updated Government Statement of Work (SOW). This amount remains unchanged for what was awarded under the UPA. This letter herby authorizes performance and invoicing up to the total agreement value of $1,769,343,470.

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.

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:
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Agreements Officer:
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Regards,

X (b) (6)

(b) (6)
Agreements Officer
(b) (6)

Attachments:
Attachment 1: MCDC RPP 20-11 Sanofi SOW 03 DEC 2020
Attachment 2: Deliverables for new FULL BAA or RFP COVID-19 Contracts

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 a reasonable chance of moving to Phase III clinical trials by January 2021 with the goal of achieving an EUA or 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 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) 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.

(b) (4) will provide Regulatory Support for (b) (4) requirements. (see Deliverable 4.6.2)

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 expreSF+® (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. **Note:** (b) (4)

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

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

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

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

Sanofi will submit a copy of the CoA for each Ph III DS lot to BARDA following release. – (see Deliverable 4.4)

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 (b) (4) 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 the (b) (4) 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) site. 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 (b) (4)

Sanofi will submit Certificates of Compliance on each Ph III DP batch following release. (see Deliverable 4.5)

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. (see Deliverable 4.1)

3.3.2 Immunogenicity study to explore antibody 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. (see Deliverable 4.2)

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)

For Repeat Dose Toxicity/DART Report see Deliverable 4.3.

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 *p.c.*
	L-subset			5	30	Day 35 *p.p.*
2	C-subset	Antigen alone (Protein S = Ag)	1HD (0.5 mL)	5	25	Day 29 *p.c.*
	L-subset			5	30	Day 35 *p.p.*
3*	C-subset	Ag + (b)	1HD (0.5 mL)	5	25	Day 29 *p.c.*
	L-subset			5	30	Day 35 *p.p.*
4*	C-subset	Ag + (b)	1HD	5	25	Day 29 *p.c.*

	L-subset		(0.5 mL)	5	30	Day 35 *p.p.*

*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 ((b) (4) 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.
- VAT0X- A safety and immunogenicity trial in pregnant women 18 years and older in their 2nd and 3rd trimester.

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. (b) (4) for Ph III will be provided by (b) (4) (see Deliverable 4.6.2). 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.

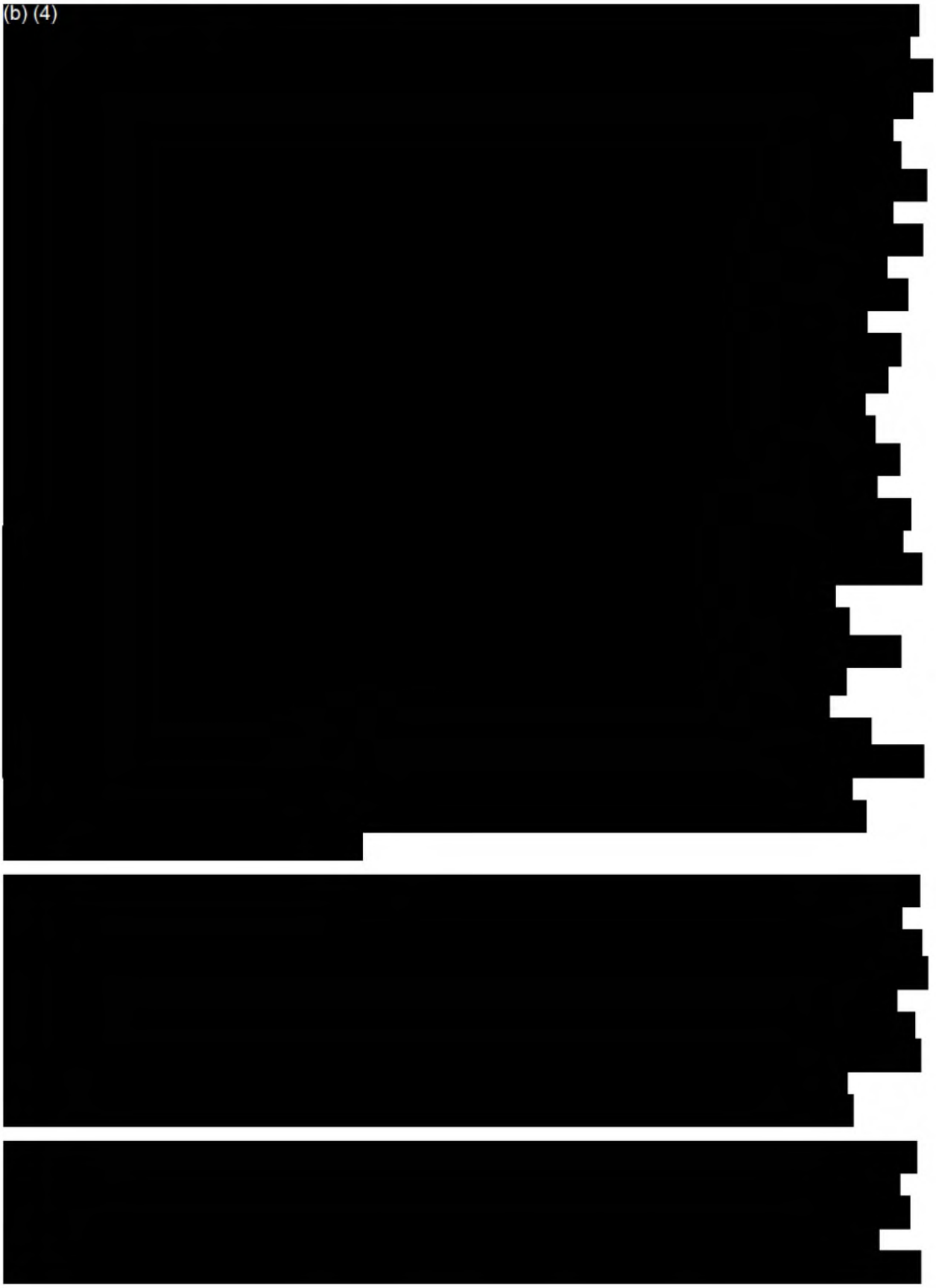
VAT02 will be a Phase III, randomized, modified double-blind, placebo-controlled, multicenter study to be conducted in 34,656 adults 18 years of age and older to evaluate the efficacy, safety and immunogenicity of SARS-CoV-2 recombinant protein with (b) (4) versus a placebo. The study groups and sample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

(b) (4)

(b) (4)

[redacted]

(b) (4)



(b) (4)

(b) (4)

[redacted]

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. (See Deliverable 4.13)

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.

(b) (4)

(b) (4)

(b) (4) [redacted]

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) [redacted]

3.4.4 VAT0X – Pregnant Women

A Phase II/III randomized, double blind, placebo controlled, safety & immunogenicity trial will be conducted in pregnant women 18 year and older in their 2nd and 3rd trimester. The trial will enroll 600 subjects randomized in a 1:1 ratio to receive either placebo or the vaccine and it is assumed each participant will receive 2 doses 21 days apart. Follow up is planned through 365 days after last vaccination with a 6-month follow-up of offspring. Blood samples will be collected on all participants at Day 1, Day 22, Day 43, Day 202 and Day 387.

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 at (b) (4) scale at (b) (4) [redacted]. Proceeding clinical manufacturing, (b) (4) [redacted] manufacturing location will commence with commercial production, at risk. Upon completion of process lock, the process will be subsequently transferred to a (b) (4) [redacted] and to a (b) (4) [redacted] for additional Drug Substance Capacity. The first 2 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)

Comparability studies will be conducted, concurrently with PPQ batch manufacturing, to demonstrate the product and process comparability between the three (3) Drug Substance manufacturing locations. (see Deliverable 4.7)

In order to accelerate the technology transfer to (b) (4) there is an increased risk of failure of batches up to and including the PPQ campaign (Engineering and PPQ). If repeat work is required, the increased costs incurred will be invoiced against milestone 5.7 *Final Tech Transfer Comparability Reports with Stability for* (b) (4) *and* (b) (4).

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 3mL fill volume and deliver 100-million doses to the US Government from the (b) (4) (see Deliverable 4.8)

- 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 500L drug products in (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 in (b) (4)
- Final presentation will be in (b) (4)
- (b) (4) (see Deliverable 4.19)
- 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.
- SP will provide DS and DP Industrial-Scale Validation Reports (see Deliverable 4.9)

Assumptions Regarding Manufacturing Requirements

- Drug substance yields are at (b) (4) (Sanofi Pasteur assumes risk of achieving targeted yield)
- Cycle time (b) (4)
- (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 the (b) (4) 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 (b) (4) 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 (b) (4) formulation batch size requirements. Final Container fill volume will target a (b) (4) 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 at (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.). (see Deliverable 4.11)

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) in September and (b) (4) in October and fill finish of drug product in October in (b) (4). Resins, flow kits and materials will be purchased to produce 50 batch equivalents with 80% of the material intended for FDS and 20% for (b) (4). PSFM media and Feed materials are proprietary products made specifically for Sanofi PSC baculoviral process by a qualified CMO. Single Use Bioreactor (SUB), mixing and process bags, filters, Q-filtration capsules, TFF cassettes will also be ordered with the exact specifications for process materials

for FDS to be determined. 10 million vials, stoppers, seals and ancillary material necessary to fill up to 100 million doses in 10 dose vials in (b) (4) will be purchased from (b) (4). The estimate includes any acceleration fees that might be needed to ensure suppliers deliver within the required time frame.

Drug product will be stored in (b) (4) Container/Per Month, (b) (4) assuming that sufficient space is available. This assumes that sufficient space could be located at (b) (4) If space isn't available, then the cost would need to take into account the incremental costs associated with the storage space. (see Deliverable 4.10)

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.

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.

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. (See Deliverable 4.14)

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) participation in such meetings to be agreed.

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.

Sanofi will notify BARDA of any scheduled FDA meetings and provide records of all official FDA communications. (see Deliverable 4.16). Sanofi will provide BARDA with all FDA inspection and enforcement documents (e.g., notice of violations, 483s, foreign inspection reports, etc.) (see Deliverable 4.17). Sanofi will provide BARDA with reports on Confirmation of FDA Registration and Listing. (see Deliverable 4.18)

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 Qtrly 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	Repeat Dose Tox and 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	3.2.3	Recipient	Unlimited Rights
4.6.1	(b) PIII Supply	8/31/2022	5.6	3.4	Recipient	Per (b)
4.6.2	(b) Regulatory Support for Licensure	8/31/2022	5.6	3.1	Recipient	Per (b)
4.7	Final Tech Transfer Comparability Reports with Stability for (b) (4)	2/22/2021	5.7	3.5.2	Recipient	Unlimited Rights
4.8	100M Doses DP Available (as Firm Fixed Price)	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. –up to 12 months)	6/30/2021	5.10	3.6.7	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	Post Licensure Clinical Trial Activities**	8/11/2023	5.13	3.4.2-4	Recipient	Unlimited Rights
4.14	Final PM Report	9/29/2023	5.14	3.7.3	Recipient	Unlimited Rights
4.15	Manufacturing Development Plan**	9/29/2023	N/A	3.7.1	Recipient	Unlimited Rights
4.16	FDA communications, meeting minutes, records	9/29/2023	N/A	3.7.4	Recipient	Unlimited Rights
4.17	FDA inspection and enforcement documents (e.g., notice of violations, 483s, foreign inspection reports, etc.)	9/29/2023	N/A	3.7.4	Recipient	Unlimited Rights
4.18	Confirmation of FDA Registration and Listing	9/29/2023	N/A	3.7.4	Recipient	Unlimited Rights

4.19	Lot Release and cGMP certification prior to shipment/Government acceptance.	9/29/2023	N/A	3.6	Recipient	Unlimited Rights
4.20	PL 115-92 Authorization Letter for DoD Medical Priorities	9/29/2023	N/A	7.4	Recipient	Unlimited Rights
4.21	Supply Chain Resiliency Plan or Sanofi Equivalent	Within 30 days after award		10.0 Appx 1	Recipient	Limited Rights
4.22	Manufacturing Data Requirement or Sanofi Equivalent	Within 30 days after award		10.0 Appx 1	Recipient	Limited Rights
4.23	Product Development Source Material & Manufacturing Reports and Projections	Within 30 days after award		10.0 Appx 1	Recipient	Limited Rights
4.24	Work Location Report	Within 30 days after award		10.0 Appx 1	Recipient	Limited Rights
4.25	Facility Security Plan or Sanofi Equivalent	Within 30 days after award		10.0 Appx 1	Recipient	Limited Rights
4.26	Quarterly Technical and Business Status Report	Mar 31st, Jun 30th, Dec 31st	5.16, 5.17, 5.18, 5.20, 5.21, 5.22 5.24, 5.25 5.26, 5.28 5.29, 5.30		Recipient	GPR
4.27	Annual Technical and Business Status Report	Annually Sept 30th	5.15, 5.19 5.23, 5.27		Recipient	GPR
4.28	Monthly Status Report	Monthly	N/A		Recipient	GPR
4.29	Final Technical and Business Status Report		5.29			
	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.*

In addition to table 4, please refer to Attachment 4.0 for common project deliverables prescribed by OWS.

In the event of any inconsistency between the Deliverables for new FULL BAA or RFP COVID-19 Contracts Attachment and the SOW, the SOW shall supersede and control.

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, (b) (4) [redacted] 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 (photos of product on pallets), 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 (b) (4) 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. Contractor is liable for risk of loss or damage product until receipt at the CDC or CDC's Designee.

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

The Milestones below represent a two phased approach toward development. Stage 1, consisting of the research and development, will be funded through a cost reimbursement basis. This method was selected because of the difficulties with estimating the costs accurately, as well as to reflect the cooperative development role the government is assuming in the development of the prototype through the tenets of the Operation Warp Speed process. Stage 2, consisting of the production of 100 million doses of the prototype, will be priced as a fixed price. This method of contracting was chosen to reflect that by Stage 2, the manufacturing process for the prototype will have been firmly established, as well as reflecting the fact that risk for commercial scale production should be shared more equally by Sanofi given it will be using its proven tooling, equipment and processes.

Sanofi will notify the Government in writing of the completion of Comparability Reports for (b) [redacted] sites, indicating the completion of Stage 1 manufacturing activities.

Sanofi will notify the Government when they have reached 75% of expenditures for a particular milestone. If it is anticipated that Sanofi will be exceeding that milestone, Sanofi will request a bilateral contract modification through the Agreement Officer.

Refunds, Rebates, and Credits. The applicable portion of any income, rebate, allowance, or other credit relating to any allowable cost and received by or accruing to the contractor shall be credited to the Government either as a cost reduction or by cash refund. The Contractor shall pay to the Government any refunds, rebates, credits, or other amounts (including interest, if any) accruing to or received by the Contractor or any assignee under this contract, to the extent that those amounts are properly allocable to costs for which the Contractor has been reimbursed by the Government. Reasonable expenses incurred by the Contractor for securing refunds, rebates, credits, or other amounts shall be allowable costs if approved by the Agreements Officer.

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	$(b) (4)
5.3	Repeat Dose Tox and DART Report	4.3	4/9/2021	$(b) (4)
5.4	CoA Completed DS PIII	4.4	12/4/2020	$(b) (4)
5.5	Certificates of Compliance DP PIII	4.5	12/6/2020	$(b) (4)
5.6	(b) PIII Supply & Regulatory Support	4.6	8/31/2022	$(b) (4)
5.7	Final Tech Transfer Comparability Reports with Stability for (b) (4)	4.7	2/22/2021	$(b) (4)
5.8	100M Doses DP Available **(as FFP – Firm Fixed Price)***	4.8	2/28/2021	$(b) (4)
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. - up to 12 months)**	4.10	6/30/2021	$(b) (4)
5.11	Final CTD / BLA Document Submitted	4.11	9/29/2023	$(b) (4)
5.12	Clinical Trial Activities (VAT02)	4.12	8/28/2022	$(b) (4)
5.13	Post Licensure Clinical Trial Activities***	4.13	9/30/2024	$(b) (4)
5.14	Final PM Report	4.14	9/29/2023	$(b) (4)
5.15	Annual Technical and Business Status Report	4.15	9/30/2020	$(
5.16	Quarterly Technical and Business Status Report	4.16	12/31/2020	$(
5.17	Quarterly Technical and Business Status Report	4.17	3/31/2021	$(
5.18	Quarterly Technical and Business Status Report	4.18	6/30/2021	$(
5.19	Annual Technical and Business Status Report	4.19	9/30/2021	$(
5.20	Quarterly Technical and Business Status Report	4.2	12/31/2021	$(
5.21	Quarterly Technical and Business Status Report	4.21	3/31/2022	$(
5.22	Quarterly Technical and Business Status Report	4.22	6/30/2022	$(
5.23	Annual Technical and Business Status Report	4.23	9/30/2022	$(
5.24	Quarterly Technical and Business Status Report	4.24	12/31/2022	$(
5.25	Quarterly Technical and Business Status Report	4.25	3/31/2023	$(
5.26	Quarterly Technical and Business Status Report	4.26	6/30/2023	$(
5.27	Annual Technical and Business Status Report	4.27	9/30/2023	$(

5.28	Quarterly Technical and Business Status Report	4.28	12/31/2023	$[redacted]
5.29	Quarterly Technical and Business Status Report	4.29	3/31/2024	$[redacted]
5.30	Quarterly Technical and Business Status Report	4.30	6/30/2024	$[redacted]
5.31	Final Technical and Business Status Report	4.31	9/30/2024	$(b)[redacted]
Period of Performance – 48 months		**Cost, No Fee**	**Total:**	**$1,769,013,470**

** Work under 5.8 will be invoiced on a lot by lot basis*
*** Insurance costs to be determined.*
****Milestone 5.13 Post Licensure Clinical Trial Activities includes three studies that would be post-marketing commitments with technical details described in SOW sections 3.4.2 thru 3.4.4.*
- *VAT03 pediatric efficacy*
- *VAT04 lot to lot consistency*
- *VAT0X pregnancy*

The pediatric study, VAT03, is planned for safety and immunogenicity, however the possibility of a much larger trial based on efficacy must be considered. It is not possible at this time to estimate trial design, protocols, subjects and other details, should they be needed. Additionally, the likelihood of VAT04 and VAT0X being conducted is uncertain. Therefore, Milestone 5.13 is not able to be definitized currently, however the possible costs must be reserved should these post marketing studies occur. As the likelihood of the activities become clearer, designs and other requirements defined the detailed estimates will be provided to support the execution of the work.

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, as specified in Milestone 5.8, 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. (see Deliverable 4.20)

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	Discovery Drive, Swiftwater, PA 18370	OWS Project Entitled: Adjuvanted Recombinant COVID-19 Vaccine Development
(b) (4)	(b) (4)	(b) (4)

Contractor	Address	Program / Contract
		(b) (6) [redacted]

12.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

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

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

AOR

NAME: (b) (6) [redacted]
EMAIL: (b) (6) [redacted]
PHONE: (b) (6) [redacted]
AGENCY NAME/DIVISION/SECTION: Department of Health and Human Services, Biomedical Advanced Research and Development Agency

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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.

Supply Chain and Distribution Tracking

Distribution Concept of Operations. BARDA, CDC, and MCM Manufacturers play an important role in the distribution of vaccines to the American people under a nationwide response. BARDA will work with the manufacturer to monitor what is in the manufacturing pipeline using the enclosed dose tracking templates (see above). BARDA will relay final drug product information as it is being released to the CDC for allocation and ordering by state public health departments. This information will be returned to BARDA as CDC replenishment orders (CDC PO) on a daily basis with shipping instructions on where to send final drug product. Manufacturers will use that information to ship vaccines or therapeutics in bulk to designated distribution centers for final distribution to end users and end user networks. BARDA will provide the contractor with a list of distribution centers and contact information prior to the start of a vaccination campaign.

Provide the following information in order to coordinate the movement and delivery of vaccine product from manufacturing locations to USG distribution centers:

- ***Provide Points of Contact information (name, title, phone, email) for manufacturing / supply chain personnel for each manufacturing, CMO, storage and distribution locations:***
    - ***Head of Manufacturing***
    - ***Production Planning***
    - ***Logistics***
    - ***Distribution***
    - ***Labeling***
- ***Provide vaccine labeling, packaging and distribution information as soon as it becomes available. At a minimum, include the following:***
    - ***Primary Container Information***
    - ***Number of doses per primary container***
    - ***Unit of Sale (carton, box, package, other)***
    - ***Quantity per Unit of Sale***
    - ***National Drug Code (NDC) or NDC-like code under EUA***
    - ***Unit of Sale dimensions (H,W, L)***
    - ***Unit of Sale weight***
    - ***Intermediate Package***
    - ***Intermediate Package dimensions***
    - ***Intermediate Package weight***
    - ***Quantity Unit of Sale per pallet***
    - ***Storage Requirements***
    - ***Stability Information***
- ***Obtain concurrence on planned shipment protocols prior to transport***
- ***If vaccine will require ultra-cold storage temperatures at the designated distribution centers, products should be packaged in 100-dose units to facilitate pick/pack process and reduce exposure of workers to ultra-cold temperatures.***
- ***Include the following DSCSA data elements, TI, TH and TS in packing lists.***
- ***Include the contract number and CDC's PO number (which BARDA will provide at the time the bulk order is submitted) on the packing list for all shipments***
- ***Include a copy of the MSDS (with QR code) in the packing list envelope with each shipment.***
- ***Send EDI 856 Advanced Shipment Notice for all products shipped to a USG directed location. CDC will provide EDI mapping specifications that include the CDC generated PO number.***

- ***Send electronic/scanned copies of all bulk shipment related documents to the COR for three-way matching on the day shipment occurs.***

Packing List

Manufacturers should include the following information on the packing lists they send with bulk shipments to the centralized depots

Rationale: Required for receiving at centralized distributor.

- ***Transaction Information (TI), Transaction History (TH), Transaction Statement (TS)***
- ***CDC Purchase Order (PO) number***

Advance Shipment Notices (ASNs)

Manufacturers should plan to transmit bulk shipment ASNs to CDC via Electronic Data Interchange (EDI)

Rationale: Required for receiving at centralized distributor.

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" or similar, on any contract/agreement that is manufacturing product, including product for clinical trial use.***

- 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 ***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, Contractor must address all concerns raised by the Government in writing

- ***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***

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 of12 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.	

NOTE: This document is the standard deliverable table for use on all COVID-19 New BAA awards, made under BARDA's BAA (BAA-18-100-SOL-00003). This document does not apply to EZ BAA awards or modifications of existing contracts. This document was reviewed by Contracting Officer (b) (6) . Modifications are possible and discretion to include or modify deliverables is the responsibility of the individual Contracting Officer working with the program team.

F.2. DELIVERABLES

ARTICLE Successful performance of the final contract shall be deemed to occur upon performance of the work set forth in the Statement of Work attached to this contract as Attachment 1 (SECTION J-List of Attachments), and upon delivery and acceptance, as required by the Statement of Work, by the Contracting Officer, or the duly authorized representative pursuant to SECTION E-Inspection and Acceptance, of the following items listed below under heading 1 "Summary of Contract Deliverables" in accordance with the stated delivery schedule.

The items specified below under heading 1 "Summary of Contract Deliverables", as described in the Statement of Work which is Attachment 1 to this contract will be required to be delivered by the date(s) specified below and in accordance with any specifications stated in SECTION D-PACKAGING, MARKING AND SHIPPING, of this contract. All reports identified below relate solely to the development activity funded under this contract:

1. **Summary of Contract Deliverables**

Unless otherwise stated, each deliverable in the table below shall be provided as one (1) electronic copy to the COR, CS, and CO as set forth in SECTION D.

In addition to or in replacement of electronic copies, the CO may direct the Contractor to submit the below deliverables via BARDA Digital Resources Portal in machine readable format.

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
01	**Meetings**		
01.1	Post Award Teleconference	The contractor shall complete an initial teleconference after contract award 1. Outline activities for the next 30 days 2. Discuss agenda items for the post-award Kickoff Meeting (01.2)	•Within one week of contract award •Contractor shall provide agenda and establish a teleconference number at least 3 business days in advance of the teleconference unless notified that BARDA will supply one •COR edits/approves and instructs contractor to distribute agenda prior to meeting by at least 2 business days •Contractor provides meeting minutes to COR within 3 business days after the meeting •COR reviews, comments and approves minutes within 10 business days
01.2	Kickoff Meeting	The Contractor shall complete a Kickoff meeting after contract award	•Within a month of contract award, pending concurrence by the contracting officer

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			•Contractor shall provide itinerary and agenda at least 5 business days in advance of site visit or virtual meeting •COR edits/approves and instructs contractor to distribute agenda prior to meeting by at least 3 business days •Contractor provides meeting minutes to COR within 3 business days after the meeting •COR reviews, comments, and approves minutes within 10 business days
01.3	Every 2 weeks Teleconference	The Contractor shall participate in teleconferences every 2 weeks, with BARDA to discuss the performance on the contract. Meeting frequency can be increased as needed during the course of the project	•Contractor provides agenda to COR no later than 2 business days in advance of meeting •COR edits/approves and instructs contractor to distribute agenda prior to meeting •Contractor distributes agenda and presentation materials at least 24 hours in advance •Contractor provides meeting minutes to COR within 3 business days of the meeting •COR reviews, comments, and approves minutes within 6 business days
01.4	Quarterly Meetings	At the discretion of the government the Contractor shall hold recurring teleconference or face-to-face Project Review Meetings up to four per year either in Washington D.C or at work sites of the Contractor or sub-contractors. Face-to-face meetings shall alternate between Washington DC and Contractor, sub-contractor sites. The meetings will be used to discuss contract progress in relation to the Program Management deliverables described below as well as study designs, technical, regulatory, and ethical aspects of the program.	•Contractor shall provide itinerary and agenda at least 5 business days, and presentation materials at least 3 business days in advance of site visit •COR edits/approves and instructs contractor to distribute agenda prior to meeting by at least 3 business days •Contractor provides meeting minutes to COR within 3 business days after the meeting •COR reviews, comments, and approves minutes within 10 business days
01.5	FDA Meetings	The Contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people (typically COR and up to 3 subject matter experts)	•Contractor shall notify BARDA of upcoming FDA meeting within 24 hours of scheduling Type A, B or C meetings OR within 24 hours of meeting occurrence for ad hoc meetings •The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to BARDA within 2 business days of receipt
01.6	Daily check in with project staff for **COVID-19 Contract**	Upon request of the Government, the Contractor shall participate in a daily check-in update with the project staff (via teleconference or email). The updates will address key cost, schedule and technical updates. Daily	•No agenda will be required for the meeting •No meeting minutes are required •Contractor will provide bulleted email updates following any call or in lieu of a call by 2PM for that day

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		updates may be shared with senior Government leaders during the COVID- 19 response and should be provided on a non-confidential basis, unless the update includes confidential information in which case Contractor shall provide the update in both confidential and non-confidential formats. Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the Government, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.	
02	**Technical Reporting**		
02.1 (Monthly) 02.2 (Annual)	Monthly & Annual Technical Progress Reports/Annual Meeting	The Monthly and Annual Technical Progress reports shall address each of the below items and be cross-referenced to the Work Breakdown Structure (WBS), Statement of Work (SOW), Integrated Master Schedule (IMS), and Contract Performance Report (CPR) – or as applicable 1. An Executive Summary highlighting the progress, issues and relevant manufacturing, non-clinical, clinical and regulatory activities. The Executive Summary should highlight only critical issues for that reporting period and resolution approach; limited to 2 pages 2. BARDA Contractor Clinical Trials Information Sheet – covering ongoing BARDA-sponsored clinical studies. This form shall provide data on relevant activities during the period covered, by study site, including: cumulative enrollment; new enrollments; screen failures; patients dropped from study; AE and SAEs; study initiation visits; activation or inactivation of study sites; investigator appointments or changes; and status of IRB/IEC review/approval/renewal review/approval/renewal 3. Progress in meeting contract milestones organized by WBS, overall project assessment, problems encountered and recommended solutions. The reports shall detail the planned and actual progress during the period covered, explaining any	•Monthly Reports shall be submitted on the 20th day of the month covering the preceding month; Annual Reports submitted on the 30th calendar day of the month after each contract anniversary. Monthly progress reports are not required for the months when the Annual Report(s) are due, and Monthly/Annual Report(s) are not due during a month when the Final Report (final version, not draft) is due (see deliverable 02.4). The COR and CO will review the monthly reports with the Contractor and provide feedback •Contractor shall provide FINAL versions of reports within 10 business days after receiving BARDA comments/edits

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		differences between the two and the corrective steps 4. A three-month rolling forecast of the key planned activities, referencing the WBS/IMS 5. A tracking log of progress on regulatory submissions with the FDA number, description of submission, date of submission, status of submission and next steps 6. Estimated and Actual Expenses a. This report shall also contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the % of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level. This section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors If the COR and CO are satisfied that the contractor's reporting is sufficient to convey this information, this section may be waived.	
02.3 (Draft) 02.4 (Final)	Draft and Final Technical Progress Report	A draft Final Technical Progress Report containing a summation of the work performed and the results obtained over the entire contract. This report shall be in sufficient detail to fully describe the progress achieved under all milestones. Report should contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained during the contract. Descriptions and rationale for activities and milestones that were not completed as planned should be provided. The draft report shall be duly marked as 'Draft' The Final Technical Progress Report incorporating feedback received from BARDA and containing a summation of the work performed and the results obtained for the entire contract PoP. The final report shall document the	•The Draft Technical Progress Report shall be submitted 75 calendar days before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP •COR will provide feedback on draft report within 15 calendar days of receipt, which the Contractor shall consider incorporating into the Final Report

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		results of the entire contract. The final report shall be duly marked as 'Final'. A cover letter with the report will contain a summary (not to exceed 200 words) of salient results achieved during the performance of the contract	
02.5 (Draft) 02.6 (Final)	Draft and Final Study Reports, Clinical and Non-Clinical	Contractor shall provide Draft and Final Clinical/Non-Clinical Study Reports to BARDA for review and comment.	•Draft report due within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA •Subcontractor prepared reports received by the Contractor shall be submitted to the COR and CO for review and comment no later than 5 business days after receipt by Contractor •The Government will provide written comments to the Draft Report for Clinical / Non-Clinical Study reports within 15 business days after the submission •Final report due 30 calendar days after receiving comments on the Draft Final Report for Clinical and Non-Clinical Studies; If corrective action is recommended, Contractor must address all concerns raised by BARDA in writing •Contractor shall consider revising reports to address BARDA's recommendations prior to FDA submission
02.7	FDA Manufacturing Reports	At BARDA's request, Contractor shall provide Manufacturing Reports to BARDA for review and comment prior to submission to FDA The COR and CO reserve the right to request within the PoP a non-proprietary Manufacturing Report for distribution within the USG	•Contractor will submit Manufacturing Reports at least 15 business days prior to FDA submission •The Government will provide written comments to the manufacturing report within 15 business days after the submission •If corrective action is recommended, Contractor must address all concerns raised by BARDA in writing •Contractor shall consider revising reports to address BARDA's concerns and/or recommendations prior to FDA submission
02.8	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	•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 daily during response operations (where a Public Health

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		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.	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, Contractor must address all concerns raised by BARDA in writing •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.
02.9	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
2.10	Pandemic Management Plan	A pandemic facility and/or operational management plan including change procedures from normal to pandemic operations Contractor will prepare an operational plan to continue operations in the event of a declared pandemic emergency.	Contractor will submit Pandemic Management Plan: • Draft within 15 days of award • Final within 30 days of award
02.11	Clinical Report during Active Enrollment Periods	The contractor shall submit detailed clinical reports during active clinical trial enrollment to include at a minimum number of subjects screened and enrolled, site activation status, safety reporting (SAEs), deviation reports and database management. Exact format TBD by COR and contractor.	Contractor shall submit Clinical Reports on a weekly basis starting when first patient is enrolled and ending when last patient is enrolled.

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
02.12	Study Protocols	The contractor shall submit draft and final nonclinical and clinical study protocols to CO and COR	Draft study protocols will be submitted to COR electronically prior to finalization. o BARDA will provide comments within 10 days of receipt of draft protocol o Contractor shall respond in writing to BARDA comments and recommendations prior to finalization of protocol. Final study protocols will be submitted to COR electronically no later than 10 business days prior to FDA submission
02.13	Final Data Submission Package	Contractor must submit a data package consisting of all raw data produced under this contract. Data may be used by BARDA for analysis, evaluation, shared with other agencies, or shared outside of the government consistent with FAR 52.227-14. This submission package must be delivered in a non-proprietary format. If clinical trial data is included, that data must be provided consistent with applicable privacy laws to protect personally identifiable information (PII).	Contractor will submit at least 15 days prior to contract end date. Partial data-sets may also be requested for delivery prior to submission of the Final Data Submission Package.
02.14	Supplemental Technical Documents, Raw Data, Tabulation Data (e.g., CDISC-compliant SDTM SAS XPT datasets), or Data Analysis (e.g., CDISC-compliant ADaM SAS XPT datasets)	Upon request and also as part of deliverables the Contractor shall provide raw data, Tabulation Data (e.g., CDISC-compliant SDTM SAS XPT datasets), or Data Analysis (e.g., CDISC-compliant ADaM SAS XPT datasets), or data report to BARDA.	Contractor shall provide the Technical Documents upon request from the CO or COR
02.15	Supply Chain and Distribution Tracking	Distribution Concept of Operations. BARDA, CDC, and MCM Manufacturers play an important role in the distribution of vaccines to the American people under a nationwide response. BARDA will work with the manufacturer to monitor what is in the manufacturing pipeline using the enclosed dose tracking templates (see above). BARDA will relay final drug product information as it is being released to the CDC for allocation and ordering by state public health departments. This information will be returned to BARDA as CDC replenishment orders (CDC PO) on a daily basis with shipping instructions on where to send final drug product. Manufacturers will use that information to ship vaccines or	Provide the following information in order to coordinate the movement and delivery of vaccine product from manufacturing locations to USG distribution centers: • Provide Points of Contact information (name, title, phone, email) for manufacturing / supply chain personnel for each manufacturing, CMO, storage and distribution locations: • Head of Manufacturing • Production Planning • Logistics • Distribution • Labeling • Provide vaccine labeling, packaging and distribution information as soon as it becomes available. At a minimum, include the following:

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		therapeutics in bulk to designated distribution centers for final distribution to end users and end user networks. BARDA will provide the contractor with a list of distribution centers and contact information prior to the start of a vaccination campaign.	• Primary Container Information • Number of doses per primary container • Unit of Sale (carton, box, package, other) • Quantity per Unit of Sale • National Drug Code (NDC) or NDC-like code under EUA • Unit of Sale dimensions (H,W, L) • Unit of Sale weight • Intermediate Package • Intermediate Package dimensions • Intermediate Package weight • Quantity Unit of Sale per pallet • Storage Requirements • Stability Information • Obtain concurrence on planned shipment protocols prior to transport • If vaccine will require ultra-cold storage temperatures at the designated distribution centers, products should be packaged in 100-dose units to facilitate pick/pack process and reduce exposure of workers to ultra-cold temperatures. • Include the following DSCSA data elements, TI, TH and TS in packing lists. • Include the contract number and CDC's PO number (which BARDA will provide at the time the bulk order is submitted) on the packing list for all shipments • Include a copy of the MSDS (with QR code) in the packing list envelope with each shipment. • Send EDI 856 Advanced Shipment Notice for all products shipped to a USG directed location. CDC will provide EDI mapping specifications that include the CDC generated PO number. • Send electronic/scanned copies of all bulk shipment related documents to the COR for three-way matching on the day shipment occurs.

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
03	**Audits**		
03.1	BARDA Audit	Contractor shall accommodate periodic or ad hoc audits and/or site visits by BARDA at all facilities involved with the development of Bulk Drug Substance and Final Drug Product. If BARDA, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to BARDA	•If issues are identified during the audit, Contractor shall submit a report to BARDA detailing the finding and corrective action(s) within 10 business days of the audit •COR and CO will review the report and provide a response to the Contractor with 10 business days •Once corrective action is completed, the Contractor will provide a final report to BARDA
03.2	FDA Audits	In the event of an FDA inspection that occurs in relation to this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector	•Contractor shall notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice •Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 1 business day of receiving correspondence from the FDA or third party •Within 10 business days of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified
03.3	QA Audits	BARDA reserves the right to participate in QA audits performed by the contractor. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action	•Contractor shall notify CO and COR a minimum of 10 business days in advance of upcoming, audits/site visits of subcontractors •Contractor shall notify the COR and CO within 5 business days of report completion. •COR and CO will review the report and provide a response to the Contractor with 10 business days

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
03.4	Risk Management Plan (RMP)	The Contractor shall provide an RMP that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance	•A Draft is due 90 business days within contract award; updates to the RMP are due concurrent with Monthly Technical Progress Reports. The contractor may choose to notify the government up to two times every three months if there are no changes from the prior submission, and not submit an update •BARDA will provide Contractor with a list of concerns in response plan submitted •Contractor must address, in writing, all concerns raised by BARDA within 20 business days of Contractor's receipt of BARDA's concerns
03.5	Integrated Master Schedule (IMS)	The contractor shall provide an IMS that illustrates project tasks, dependencies, durations throughout the period of performance, and milestones (GO/NO-GO). The IMS must map to the WBS, and provide baseline, and actual or forecast dates for completion of tasks	•The IMS is to be submitted in both PDF and Microsoft Project Form to the COR •The first Draft of the IMS is due 30 business within contract award •The Government will request revisions within 10 business days, at which point the schedule baseline for the period of performance will be set •Thereafter an updated IMS is due concurrent with Monthly Technical Progress Reports •During a declared Public Health Emergency, the IMS is to be delivered within 10 days of contract award, updates are due weekly, and any significant change (I.e. a change which would impact the schedule by greater than one week) must be reported immediately to the COR and/or designee.
03.6	Deviation Notification and Mitigation Strategy	Process for changing IMS activities associated with cost and schedule as baselined. Contractor shall notify BARDA of significant proposed changes the IMS defined as increases in cost above 5% or schedule slippage of more than 30 days, which would require a PoP extension. Contractor shall provide a high level management strategy for risk mitigation	•Due at least 10 business days prior to the Contractor anticipating the need to implement changes
03.7	Incident Report	Contractor shall communicate to BARDA and document all critical programmatic concerns, issues, or probable risks that have or are likely to significantly impact project schedule and/or cost and/or performance. "Significant" is frequently defined as a 10% or greater cost or schedule variance within a control account, but should be confirmed in consultation with the COR. Incidents that present liability to the project even without	•Due within 48 hours of activity or incident or within 24 hours for a security activity or incident •Email or telephone with written follow-up to COR and CO •Additional updates due to COR and CO within 48 hours of additional developments •Contractor shall submit within 5 business days a Corrective Action Plan (if deemed

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		cost/schedule impact, such as breach of GCP during a clinical study, must also be reported	necessary by either party) to address any potential issues •If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by BARDA within 5 business days of receiving such concerns
03.8	Quality Technical Agreement	Contractor and BARDA RQA shall establish a Quality Technical Agreement	•Contractor shall collaborate with BARDA RQA to establish QTA within 10 business days of project start
04	**Advanced R&D Products**		
04.1	Technical Documents	Upon request, Contractor shall provide CO and COR with deliverables from the following contract funded activities: quality agreements between contractors and sub-contractors, process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The CO and COR reserve the right to request within the PoP a non-proprietary technical document for distribution within the Government	•Contractor shall provide technical document within 10 business days of CO or COR request. Contractor can request additional time on an as needed basis •If corrective action is recommended, the Contractor must address, in writing, concerns raised by BARDA in writing
04.2	Animal Model or Other Technology Transfer Package	Contractor shall provide Animal Model or Other Technology Transfer Package containing relevant methodology and data sufficient to enable other practitioners in the field to successfully replicate experimental conditions developed and tested with BARDA support	•Contractor shall provide a draft package within 20 business days of COR or CO request •Contractor shall revise the package to address BARDA's concerns, recommendations and/or requests for additional detail
04.3	Raw Data, Tabulation Data (e.g., CDISC-compliant SDTM SAS XPT datasets), or Data Analysis (e.g., CDISC-compliant ADaM SAS XPT datasets)	Contractor shall provide raw data, Tabulation Data (e.g., CDISC-compliant SDTM SAS XPT datasets), or Data Analysis (e.g., CDISC-compliant ADaM SAS XPT datasets), to BARDA upon request	•Contractor shall provide raw data, Tabulation Data (e.g., CDISC-compliant SDTM SAS XPT datasets), or Data Analysis (e.g., CDISC-compliant ADaM SAS XPT datasets) to CO and COR within 20 business days of request
04.4	Publications	Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to BARDA for review prior to submission. Acknowledgment of BARDA funding must be included as noted in contract articles H.9 and H.24	• Contractor must submit all manuscript or scientific meeting abstract to PO, CO and BARDAClearance@hhs.gov prior to submission/presentation by 30 business days for manuscripts and 15 business days for abstracts or posters • Contractor must address in writing all concerns raised by BARDA in writing • Final submissions shall be submitted to BARDA concurrently or no later than one (1) calendar day of its submission

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
04.5	Contractor Clinical Publication Timeline and USG Right to Publish Data	The Contractor and Government are committed to transparent and timely publication of clinical trial data to ensure rapid distribution of information during the COVID-19 Pandemic. Within 30 days of the primary analysis, results from clinical studies funded in whole or in part under this contract and consistent with Good Publications Practices. Sponsor must publish the primary endpoint analysis. Within 90 days of the of study end date [last subject last visit] for studies funded in part or whole under this contract and consistent with Good Publication Practices sponsor shall publish clinical trial data. If the contractor does not elect to publish data, Contractor shall provide CO and COR with clinical trial data to support the government publication of data as deemed appropriate by the government, without the contractor involvement. The government reserves the right to publish a counter-analysis of the data.	• Contractor shall notify CO and within 30 of primary analysis results and study end date [last subject last visit] if they plan not to publish data. • Within 10 calendar days of a request for clinical data from the CO, the Contractor shall provide CO with requested data, information and materials in the form(s) requested by the government, to support the government publication of the clinical trial data funded in part or whole under this contract
04.6	Contractor Nonclinical Publication Timeline and USG Right to Publish Data	The Contractor and Government are committed to transparent and timely publication of nonclinical data to ensure rapid distribution of information during the COVID-19 Pandemic. Within 90 days of the of study end date [audited or QC'd draft final report prepared and reviewed by the Government] for studies funded in part or whole under this contract and consistent with Good Publication Practices sponsor shall submit nonclinical study data for publication to a peer reviewed journal. If the contractor does not elect to publish data, Contractor shall provide CO and COR with nonclinical data to support the government publication of data as deemed appropriate by the government, without the contractor involvement. The government reserves the right to publish a counter-analysis of the data.	• Contractor shall notify CO within 30 days of study end date [audited or QC'd draft final report prepared and submitted for Government review] if they plan not to publish data. •Within 10 calendar days of a request for nonclinical data from the CO, the Contractor shall provide CO with requested data, information and materials in the form(s) requested by the government, to support the government publication of the nonclinical trial data funded in part or whole under this contract

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
05	**Regulatory Documents**		
5.1	FDA Correspondence	The Contractor shall memorialize any correspondence between Contractor and FDA and submit to BARDA	•Contractor shall provide copies of any FDA correspondence within 2 business days of correspondence
5.2	FDA Submissions	The Contractor shall provide BARDA the opportunity to review and comment upon all draft submissions before submission to the FDA. Contractor shall provide BARDA with an electronic copy of the final FDA submission. All documents shall be duly marked as either "Draft" or "Final"	•Contractor shall submit draft FDA submissions to BARDA at least 15 business days prior to FDA submission •BARDA will provide feedback to Contractor within 10 business days of receipt •The Contractor must address, in writing, its consideration of all concerns raised by BARDA prior to FDA submission •Final FDA submissions shall be submitted to BARDA concurrently or no later than 1 calendar day of submission
06	**Press Releases**		
6.1	Press Releases	Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases	• Contractor shall submit to the PO, CO and BARDAClearance@hhs.gov an advanced copy of any press release to this contract not less than 5 business days prior to the issuance of the press release • The CO must approved the advanced copy 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
07	**COVID19 Vaccines Only**		
7.1	Packing List	Manufacturers should include the following information on the packing lists they send with bulk shipments to the centralized depots Rationale: Required for receiving at centralized distributor.	• Transaction Information (TI), Transaction History (TH), Transaction Statement (TS) • CDC Purchase Order (PO) number •
7.2	Advance Shipment Notices (ASNs)	Manufacturers should plan to transmit bulk shipment ASNs to CDC via Electronic Data Interchange (EDI) Rationale: Required for receiving at centralized distributor.	

2. Detailed Description of Select Contract Deliverables

A. Monthly and Annual Progress Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with

this Article F of this contract, and in the Statement of Work, attached to this contract as Attachment 1 (SECTION J-List of Attachments).

i. **Monthly Progress Report**

This report shall include a description of the activities during the reporting period, 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 shall consist of each calendar month.

The Contractor shall submit a Monthly Progress Report according to the dates set forth in the summary table ("Summary of Contract Deliverables") under this article. The progress report shall conform to the requirements set forth in the DELIVERIES Article in SECTION F of this contract.

The format should include:

- A cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission;
- SECTION I – EXECUTIVE SUMMARY
- SECTION II - PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g., evaluating, and managing subcontractor performance, and personnel changes).
- SECTION II Part C: TECHNICAL PROGRESS - For each activity related to Gantt chart, document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project.
- SECTION II Part D: PROPOSED WORK - A summary of work proposed related to Gantt chart for the next reporting period and preprints/reprints of papers and abstracts.
- SECTION III: Estimated and Actual Expenses.
  a. This section of the report shall contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between

the % of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level.

b. This section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors.

A Monthly Progress Report will not be required in the same month that the Annual Progress Report is submitted.

ii. **Annual Progress Report**

This report shall include a summation of the results of the entire contract work for the period covered. Monthly Progress Reports shall not be submitted in the same month when an Annual Progress Report is due. Furthermore, an Annual Progress Report will not be required for the period when the Final Report is due.

The first Annual Progress Report shall be submitted in accordance with the date set forth in the table ("Summary of Contract Deliverables") under ARTICLE F.2. of this contract. The progress report shall conform to the requirements set forth in the DELIVERIES Article in SECTION F of this contract.

Each Annual Progress Report shall include:

- A Cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and email address; and the date of submission;
- SECTION I: EXECUTIVE SUMMARY - A brief overview of the work completed, and the major accomplishments achieved during the reporting period.
- SECTION II: PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A high level summary of critical meetings, etc. that have taken place during the reporting period. Include progress on administration and management to critical factors of the project (e.g. regulatory compliance audits and key personnel changes).
- SECTION II Part C: TECHNICAL PROGRESS - A detailed description of the work performed structured to follow the activities and decision gates outlined at the Integrated Baseline Review and as described in the Integrated Master Plan. The Report should include a description of any problems (technical or financial) that occurred or were identified during the reporting period, and how these problems were resolved.
- SECTION II Part D: PROPOSED WORK - A summary of work proposed for the next year period to include an updated Gantt Chart.

- SECTION III: Estimated and Actual Expenses.
  a. This section of the report shall contain a narrative or table detailing whether there were discrepancies between estimated and actual expenses over the past year. Actual expenses should be broken down to the appropriate WBS level. This section of the report should also contain estimates for outstanding costs for the previous year which may have been incurred, but not yet billed.

Contractor also should include the following in the Annual Progress Report:

1. Copies of manuscripts (published and unpublished), abstracts, and any protocols or methods developed specifically under the contract during the reporting period; and
2. A summary of any Subject Inventions per the requirements under FAR Clause 52.227-11.

iii. **Draft Final Report and Final Report**

These reports are to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Report and Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract. An Annual Progress Report will not be required for the period when the Final Report is due. The Draft Final Report and the Final Report shall be submitted in accordance with the dates set forth in the table ("Summary of Contract Deliverables") under ARTICLE F.2. of this contract. The report shall conform to the following format:

1. Cover page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address and submission date.

2. SECTION I: EXECUTIVE SUMMARY - Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.

3. SECTION II: RESULTS - A detailed description of the work performed related to WBS and Gantt chart, the results obtained, and the impact of the results on the scientific and/or public health community including a listing of all manuscripts (published and in preparation) and abstracts presented during the entire period of performance and a summary of all inventions.

Draft Final Report: The Contractor is required to submit the Draft Final Report to the Contracting Officer's Representative and Contracting Officer. The Contracting Officer's Representative and Contracting Officer will review the Draft Final Report and provide the Contractor with comments in accordance with the dates set forth in ARTICLE F.2. of this contract.

Final Report: The Contractor will deliver the final version of the Final Report on or before the completion date of the contract. The final version shall include or

address the COR's and CO's written comments on the draft report. Final Report shall be submitted on or before the completion date of the contract.

iv. **Summary of Salient Results**

The Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

v. **Audit Reports**

Within thirty (30) calendar days of an audit related to conformance to FDA regulations and guidance, including adherence to GLP, GMP, GCP guidelines, the Contractor shall provide copies of the audit report (so long as received from the FDA) and a plan for addressing areas of nonconformance to FDA regulations and guidelines for GLP, GMP, or GCP guidelines as identified in the final audit report.

vi. **Other Technical Reports**

1. **Draft Report for Clinical and Non-Clinical Studies and Final Report for Clinical and Non-Clinical Studies**

- The clinical trial reports shall follow the format of International Conference on Harmonization document ICH E3 "Guideline for Industry on Structure and Content of Clinical Study Reports"
- Draft Final Report for Clinical and Non-Clinical Studies funded by this contract will be submitted to the Contracting Officer's Representative and Contracting Officer (CO) for review and comment within the time frames set forth in the table ("Summary of Contract Deliverables") under ARTICLE F.2.
- Subcontractor prepared reports received by the Contractor shall be submitted to the Contracting Officer's Representative and Contracting Officer (CO) for review and comment as set forth by the table in this Article. Contractor shall consider revising reports to address BARDA's recommendations prior to FDA submission.
- The Government shall provide written comments to the Draft Final Report for Clinical and Non-Clinical Studies in accordance with the dates set forth by the table in this Article.
- The comprehensive Final Report for Clinical and Non-Clinical Studies will be submitted to the Contracting Officer and the Contracting Officer's Representative set forth by the table in this Article.

2. **Supplemental Technical Documents**

Upon request, Contractor shall provide CO and COR with the following contract funded documents as specified below but not limited to: Process Development Reports; Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, Contractor/Subcontractor Standard Operating Procedures (SOP's), Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The CO and COR reserve the right to request within the Period of Performance a non-proprietary technical document for distribution within the USG. Contractor shall provide technical document

within 10 business days of CO or COR request. Contractor can request additional time on an as needed basis. If edits are recommended, the Contractor must address, in writing, concerns raised by BARDA.

B. Deliverables Arising from FDA Correspondence

i. **FDA Meetings**

The Contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people.

- Contractor shall notify BARDA of upcoming FDA meeting within 24 hours of scheduling Type A, B or C meetings OR within 24 hours of meeting occurrence for ad hoc meetings.
- The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to BARDA within 5 business days of receipt. All documents shall be duly marked as either "Draft" or "Final."

ii. **FDA Submissions**

The Contractor shall provide BARDA all documents submitted to the FDA. Contractor shall provide BARDA with an electronic copy of the final FDA submission. All documents shall be duly marked as either "Draft" or "Final."

- When draft documents are submitted for BARDA review, BARDA will provide feedback to Contractor within 10 business days of receipt.
- When BARDA reviews draft documents, the Contractor shall revise their documents to address BARDA's written concerns and/or recommendations prior to FDA submission.
- Final FDA submissions shall be submitted to BARDA concurrently or no later than 1 calendar day of their submission to FDA.

iii. **FDA Audits**

In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR) within five (5) business days after the Contractors receipt of those documents. The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.

- Contractor shall notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice.

- Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 5 business days of receiving correspondence from the FDA, Subcontractor, or third party.
- Within 10 business days of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.

iv. **Manufacturing Campaign Reports**

Contractor shall provide Manufacturing Campaign Reports to BARDA for review and comment prior to submission to FDA.

The COR and CO reserve the right to request within the Period of Performance (PoP) a non-proprietary Manufacturing Campaign Report for distribution within the USG.

- Contractor will submit Manufacturing Campaign Reports at least 15 business days prior to FDA submission.
- If corrective action is recommended, Contractor must address, in writing, all concerns raised by BARDA.
- Contractor shall revise the reports to address BARDA's concerns and/or recommendations prior to FDA submission.
- Final FDA submission shall be submitted to BARDA concurrently or no later than 1 business day after submission to the FDA.

v. **Other FDA Correspondence**

The Contractor shall memorialize any correspondence between Contractor and FDA and submit to BARDA. All documents shall be duly marked as either "Draft" or "Final." Contractor shall provide written summary of any FDA correspondence within 5 business days of correspondence.

i. **Risk Management Plan**

The Contractor shall provide a Risk Management Plan that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance.

- Due within 90 days of contract award
- Contractor provides updated Risk Management Plan in Monthly Progress Report
- BARDA shall provide Contractor with a written list of concerns in response plan submitted
- Contractor must address, in writing, all concerns raised by BARDA within 20 business days of Contractor's receipt of BARDA's concerns.

3. Contract WBS Milestones/Deliverables and Technical Deliverables
(This section is completed by individual project teams and below are a few examples)

No.	GO-NOGO Milestone *	Milestone Definition	Success Criteria	Failure Criteria	Deliverable	WBS Element	CLIN	CLIN Initiated by Milestone Success
1.	A1	Feasibility of XXX####: effective clinical dose regimen	Studies demonstrate an effective dose of XXX####: with a potentially acceptable safety margin, in combination with a (drug) be defined	Studies fail to demonstrate an effective dose of XXX####: with a potentially acceptable safety margin, in combination with a (drug) can be defined	Draft Study Reports	1.3.3.5 and 1.3.7.4	1	
2.	A	Pre IND meeting	FDA general acceptance of proposed data package to support an IND	FDA non acceptance of data package to support an IND	Meeting Minutes	1.5.1.1	1	
3.								2
4.	A	Phase 1 First in Human study	XXX#### is well tolerated with no significant safety signal observed	Any safety or PK interaction which necessitates termination of clinical development	Study Report	1.4.1.3	1	
5.								
6.	C	Phase 1 renal impairment study	Definition of dose adjustment factor for XXX####+/-durg in enrolled subgroups	Dose adjustment in enrolled patient subgroups cannot be predicted	Availability of top-line data	1.4.1.2	2	3

No.	GO-NOGO Milestone *	Milestone Definition	Success Criteria	Failure Criteria	Deliverable	WBS Element	CLIN	CLIN Initiated by Milestone Success
7.	D	Manufacturing of cGMP batch Phase 3 Campaign #1	Material released	Material not released	Release certificate	1.6.3.3.2.1	3	4
8.								6
9.	E	End of phase 2 meeting	FDA consider Phase 3 strategy acceptable	FDA consider phase 3 strategy unacceptable	Meeting minutes	1.5.1.4	3	
10.								

Appendix: BARDA SOP for Product Acceptance and Model Contract Language

- Acceptance: 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 substance and/or drug product.
    - 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 Agreements Officer (AO) and 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 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 AO will correspondingly notify the Contractor of acceptance or rejection. HHS reserves the right to audit, either by HHS and/or HHS 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 [Date], and, as such, the Government 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 Government 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 US Government representative, and with reasonable notice (i.e., not less than 24 hours). HHS reserves the right to conduct an audit, either by HHS and/or HHS 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 HHS, 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 HHS. Report interim data and results to HHS 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 HHS.
- 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 AO 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 HHS.

- The contractor may request to arrange and hold FDP at a USG government 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 outline in FAR Clause 52.246-16 (below) apply.
- The Contractor cannot reclaim title to product upon acceptance by the Government. Prior to expiration or termination of this contract, 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 or to state and local health agencies and/or other providers.
    - The Government 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.

52.246-16 – Responsibility for Supplies (Apr 1984)
(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. Contractor is liable for risk of loss or damage product until receipt at the final destination.
(d) Under paragraph (b) of this section, the Contractor 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.

Appendix II: BARDA Deliverables for RQA Product Acceptance

Acceptance Documents	The following pre-delivery documents are a requirement of each manufacturer: SDS, Sample Label, CoC and COA
Document Delivery	Documents will be shared to a mutually specified sharing platform, such as Box
Lot Release Timeline	An EUA release means the product is ready for shipment immediately or <4 hours later
Document Timeline	Pre-delivery documents are to be provided to BARDA and the FDA for each and every lot no later than manufacturer lot release
Invoicing Timeline	Invoicing timeline should be specified under one of the following conditions: a) Upon receiving **CoC or CoA** b) Upon successful hand off to CDC or Designee