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

REPLY TO
ATTENTION OF

30 July 2020

Army Contracting Command – New Jersey
ACC-NJ, Building 10
Picatinny Arsenal, NJ 07806

SUBJECT: Technical Direction Letter for Medical CRBN Defense Consortium (MCDC), Request for Prototype Proposals (RPP) 20-11, Objective PRE-20-11 for Undefinitized "Adjuvanted Recombinant COVID-19 Vaccine Development" Sanofi Pasteur, Inc. (Sanofi)

REF: Sanofi Request for Technical Direction Letter, RPP 20-11 under OTA W15QKN-16-9-1002 for Objective PRE-20-11, dated 30 July 2020

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

Dear (b) (6),

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

The Government received the undefinitized Rough Order of Magnitude (ROM) proposal update on 24 July 2020, and reviewed the costs and documentation accordingly. Based upon the acceptable update of Sanofi's proposal for "Adjuvanted Recombinant COVID-19 Vaccine Development" and 1) The Project Agreement Recipient's concurrence with the requirements included in the Government SOW; 2) An acceptable milestone schedule that meets SOW requirements, and; 3) The ROM that has been analyzed and concurred to by the Government, you are hereby directed to issue a Undefinitized Project Agreement to Sanofi for the subject project. The total project value will be determined fair and reasonable via a subsequent modification to the project agreement.

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

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

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

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

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

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

Points of Contact:

Agreements Specialist:
(b) (6)
E-mail (b) (6)
Phone: (b) (6)

Agreements Officer:
(b) (6)
E-mail: (b) (6)
Phone: (b) (6)

Regards,

X (b) (6)

(b) (6)
Agreements Officer

Attachments:
Attachment 1: MCDC RPP 20-11 Sanofi SOW
Attachment 2: UPA Addendum - MCDC RPP 20-11 – Sanofi

Statement of Work
For Adjuvanted Recombinant COVID-19 Vaccine Development

RPP #: 20-11
Project Identifier: MCDC2011-005
Consortium Contractor: Sanofi Pasteur
Title of Proposal: Adjuvanted Recombinant COVID-19 Vaccine Development
Requiring Activity: Joint mission between the Department of Health and Human Services and Department of Defense to combat COVID-19

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

1.1 Introduction

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

1.2 Scope of the Prototype Project

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

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

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

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

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

1.3 Follow-on Production

In accordance with 10 U.S.C.2371b(f), and upon a determination that the Product Development or Manufacturing Capability portions of the prototype project for this transaction have been successfully completed, this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction without the use of competitive procedures. The prototype vaccine candidate will undergo Clinical Studies through Phase III ultimately supporting FDA licensure of the vaccine and cGMP manufacturing process.

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

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

1.4 Caveats and Risks

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

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

1.5 PREP Act

In accordance with the Public Readiness and Emergency Preparedness Act ("PREP Act"), Pub. L. No. 109-148, Division C, Section 2, as amended (codified at 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e), as well as the Secretary of HHS's Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020, effective Feb. 4, 2020), and amended on April 15, 2020, 85 Fed. Reg. 21012 (together, the "Prep Act Declaration"):

(i) This Agreement is being entered into for purposes of facilitating the manufacture, testing, development, distribution, administration, and use of "Covered Countermeasures" for responding to the COVID-19 public health emergency, in accordance with Section VI of the PREP Act Declaration;

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

(iii) Contractor is a "Covered Person" to the extent it is a person defined in Section V of the PREP Act Declaration.

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

2.0 APPLICABLE REFERENCES

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

3.0 REQUIREMENTS

3.1 Regulatory Planning

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

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

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

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

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

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

3.2 Clinical Materials Manufacturing

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

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

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

3.2.1 Description of Clinical Drug Substance Manufacturing

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

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

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

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

- Cell Culture Expansion
- WVB Expansion
- Protein Production

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

- (b) (4)
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- (b) (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 Swiftwater manufacturing site.

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

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

The Contractor will conduct downstream process development activities to support manufacturing including:
- Formulation
- Filling
- Visual Inspection
- Clinical Labelling and Packaging

3.2.3 Description of Drug Product Testing

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

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

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

3.3 Non-Clinical Activities

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

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

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

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

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

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

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

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

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

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

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

The study group composition is summarized in 3.3.4 below:

Table 3.3.4 DART Study Group Composition

Study Gps	Study Subsets	Treatment	Dose-level (Dose-volume) per injection	Total # of injections	# of animals	Date of sacrifice
1	C-subset	Control (0.9%NaCl)	1HD (0.5 mL)	5	25	Day 29 *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 + AF03	1HD (0.5 mL)	5	25	Day 29 *p.c.*
	L-subset			5	30	Day 35 *p.p.*
4*	C-subset	Ag + (b) (4)	1HD (0.5 mL)	5	25	Day 29 *p.c.*
	L-subset			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 (AF03 and (b) (4) is planned. This Ph I/II trial will evaluate two different doses of recombinant protein antigen administered as either a single vaccination or two vaccinations 21 days apart. Immunogenicity assessment includes Neutralizing antibodies to wild-type SARS-CoV-2, binding antibodies measured by ELISA & cellular immune responses for Th1/Th2 immune response characterization. SP is planning to conduct an analysis on data collected up to 21 days after the final vaccination and submit a limited data package for FDA review prior to progression to later phase clinical development. Supplemented by non-clinical studies, this safety and immunogenicity data will be the basis for selecting one of the formulations to progress to the later stage of clinical development.

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

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

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

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

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

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

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

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3.4.2 VAT03 - Clinical Plan for Pediatric Development

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

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

(b) (4)

(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]

3.5 Commercial-Scale Drug Substance

The Drug Substance Manufacturing Process will be locked concurrently with the Phase III clinical manufacturing process. Phase III clinical manufacturing will occur (b) (4) [redacted] will commence with commercial production, at risk. (b) (4) [redacted] The first 3 lots of Drug Substance will be designated for Phase III Clinical study material and the remaining manufacturing will be designated for follow on production.

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

3.5.2 Technology Transfer

(b) (4) [redacted]

(b) (4)

(b) (4)

(b) (4)

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

3.5.3 Analytical Transfer

In order to streamline the transfer activities and to minimize the changes between (b) (4) sites, one (1) analytical testing reference site will be utilized. (b) (4) The exceptions to this strategy are time sensitive tests (i.e. microbial) and in-process controls (IPCs). These tests will be transferred to the Drug Substance CMO following standard analytical transfer methodology.

3.6 Commercial-Scale Drug Product

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

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

manufacturing.

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

Assumptions Regarding Manufacturing Requirements

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

3.6.1 Formulation

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

3.6.2 Filling

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

3.6.3 Inspection

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

3.6.4 In-Process Quality Control Sampling

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

3.6.5 Stability Testing

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

3.6.6 Documentation / Reporting

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

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

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

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

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

(b) (4)

(b) (4)

3.6.8 Shipping Demonstration

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

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

3.7 Management and Reporting

3.7.1 Project Management

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

3.7.2 Technical Progress Reports

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

3.7.3 Final Report

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

3.7.4 Meetings

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

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

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

(b) (4) .

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

4.0 DELIVERABLES

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

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

4.13	Clinical Trial Activities (VAT03)*	8/11/2023	5.13	3.4.2	Recipient	Unlimited Rights
4.14	Clinical Trial Activities (VAT04)	6/4/2022	5.14	3.4.2	Recipient	Unlimited Rights
4.15	Final PM Report	9/29/2023	5.15	3.7.3	Recipient	Unlimited Rights
4.16	Manufacturing Development Plan**	9/29/2023	N/A	3.7.1	Recipient	Unlimited Rights
4.17	FDA communications, meeting minutes, records	9/29/2023	N/A	3.1	Recipient	Unlimited Rights
4.18	FDA inspection and enforcement documents (e.g., notice of violations, 483s, foreign inspection reports, etc.)	9/29/2023	N/A	3. 1	Recipient	Unlimited Rights
4.19	Confirmation of FDA Registration and Listing	9/29/2023	N/A	3.1	Recipient	Unlimited Rights
4.20	Lot Release and cGMP certification prior to shipment/Government acceptance.	9/29/2023	N/A	4.1	Recipient	Unlimited Rights
4.21	PL 115-92 Authorization Letter for DoD Medical Priorities	9/29/2023	N/A	7.4	Recipient	Unlimited Rights
4.22	Supply Chain Resiliency Plan or Sanofi Equivalent	Within 30 days after award		10.0 Appendix 1	Recipient	Limited Rights
4.23	Manufacturing Data Requirement or Sanofi Equivalent	Within 30 days after award		10.0 Appendix 1	Recipient	Limited Rights
4.24	Product Development Source Material & Manufacturing Reports and Projections	Within 30 days after award		10.0 Appendix 1	Recipient	Limited Rights
4.25	Work Location Report	Within 30 days after award		10.0 Appendix 1	Recipient	Limited Rights
4.26	Facility Security Plan or Sanofi Equivalent	Within 30 days after award		10.0 Appendix 1	Recipient	Limited Rights
4.27	Quarterly Technical and Business Status Report	Mar 31st, Jun 30th, Dec 31st	5.17, 5.18, 5.19, 5.21, 5.22, 5.23, 5.25, 5.26, 5.27, 5.29, 5.30, 5.31		Recipient	GPR
4.28	Annual Technical and Business Status Report	Annually Sept 30th	5.16, 5.20, 5.24, 5.28, 5.32		Recipient	GPR
4.29	Monthly Status Report	Monthly	N/A		Recipient	GPR
	Period of Performance: 48 months					

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

4.1 Acceptance of Vaccine Doses

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

- Unless otherwise mutually agreed upon by the parties, drug product shall be shipped, trackable by GPS, to the Government-designated sites within the continental United States.
- Contractor will retain physical risk of loss for all product stored as vendor-managed inventory until delivery and accepted by Government at government-designated site.
- Contractor will notify government (AO, AOR, and BARDA RQA Quality Branch) of any storage or quality deviation for product held in VMI, within 3 calendar days
- To the extent that Contractor is responsible for the correction, repair or replacement of Government property held in vendor-managed inventory and replacement upon loss or damage is feasible, the Government will accept replacement of such property.
- Vendor-managed storage of product manufactured under this agreement is supported through 30 June 2021, and, as such, the USG must either (a) take possession on or before this date and provide Contractor with disposition instructions in sufficient time to transfer physical material from Contractor by this date or (b) bilaterally modify this agreement to extend the period of vendor management of storage prior to this date.
- The USG understands that prices identified in this contract include insurance costs applicable to material that will become Government property, including product stored as vendor-managed inventory.

- USG right to inspect product: The AO and/or the AOR may perform inspection of materials and services. Inspections of material created under this contract may be made by a duly authorized USG representative, and with reasonable notice (i.e., not less than 24 hours). The USG reserves the right to conduct an audit, either by Government and/or Government designee(s), of the facilities used under this contract and all records related to the manufacture, testing, and storage of the product.
  - The manufacturer will make the necessary efforts to arrange and hold Final Drug Product (FDP) at a facility under their control. In this case, the manufacturer will:
    - Provide temperature-controlled storage at the manufacturer's site approved by the USG, according to cGMP and the Contractor's product specifications.
    - Store bulk lots and final containers physically segregated from other products
    - Ensure proper labeling of stored materials as USG property.
    - Execute stability testing of stored material in a manner consistent with the stability testing plan approved by the AOR. Report interim data and results to the AOR on a monthly basis.
    - Appropriately identify reserve samples that are representative of each lot of drug substance and drug product shall be retained. The reserve samples consist of at least twice the quantity necessary for all tests required to determine whether the drug substance and drug product meets its established specifications including a minimum of 60 months of stability testing.
    - Ensure stored materials are compliant with the Contractor's internal quality control system and are ready for use in further cGMP governed manufacturing of clinical material or licensed doses as directed by the USG.
    - Provide the government access to review the security systems in place and request updates as needed.
    - Include in monthly report inventory for drug substance and/or drug product (lot number, number of lots, number of vials), including inventory quantity changes, current quantity, storage facility/location, manufacturing date, latest

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

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

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

Responsibility for Supplies

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

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

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

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

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

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

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

5.0 MILESTONE PAYMENT SCHEDULE

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

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

** Insurance costs to be determined.*

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

5.1 Most Favored Nation Clause

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

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

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

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

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

6.0 SHIPPING PROVISIONS

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

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

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

7.0 INTELLECTUAL PROPERTY and REGULATORY RIGHTS

7.1 Patent Rights

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

7.2 Technical Data Rights

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

7.3 Confidential Information

7.3.1 General

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

7.3.2 Exclusion

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

7.4 Regulatory Rights

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

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

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

a. Communications. Contractor will provide the Government with all communications and summaries thereof, both formal and informal, to or from FDA regarding the Technology and ensure that the Government representatives are invited to participate in any formal or informal Sponsor meetings with FDA;

b. DoD Medical Product Priority. PL 115-92 allows the DoD to request, and FDA to provide, assistance to expedite development of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. The Awardee recognizes that only the DoD can utilize PL 115-92. As such, the Awardee will work proactively with the Government to leverage this law to its maximum potential under this Project Agreement. The Awardee shall submit Public Law 115-92 Sponsor Authorization Letter that will be delivered to the designated OWS POC(s) within 30 days of award.

c. Rights of Reference. To the extent necessary or useful to exercise the Government's rights under the license grants in Section 7 of this Project Agreement and subject to the restrictions set forth in that section, Sanofi Pasteur hereby grants to the Government and its permitted sublicensees a limited "right of reference or use" (as that term is defined in 21 C.F.R. § 314.3(b), as amended from time to time) strictly for COVID-19 or other Material Threat (as defined at Section 319 of the Public Health Service Act) Purposes to Sanofi Pasteur's filings to the FDA in connection with the Regulatory Application (excluding such right of reference or use for (b) (4) and Sanofi Pasteur shall provide appropriate notification of the Government's access and reference rights to the applicable regulatory authorities requested by the Government for the limited purposes described above. Sanofi Pasteur agrees to provide a letter of cross-reference to the Government and file such letter with the appropriate FDA office. This provision is in addition to any rights in technical data described earlier in this document, excluding with respect to (b) (4)

8.0 ENSURING SUFFICIENT SUPPLY OF THE PRODUCT

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

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

a. Sanofi gives written notice, required to be submitted to the Government no later than 15 business days, of:

i. any formal management decision to terminate manufacturing of this product vaccine prior to delivery of 100 million doses to USG, or;

ii. any formal management decision to discontinue sale of this product vaccine to the Government prior to delivery of 100 million doses to USG; or

iii. any filing that anticipates Federal bankruptcy protection; and

b. Sanofi has submitted an Emergency Use Authorization under §564 of the FD&C Act or a biologics license application provisions of §351(a) of the Public Health Service Act (PHSA).

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

a. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Sanofi Background Patent, Copyright, other Sanofi Intellectual Property, Sanofi Know-How, Sanofi Technical Data rights necessary to manufacture or have manufactured the vaccine;

b. necessary FDA regulatory filings or authorizations owned or controlled by Sanofi related to this product vaccine and any confirmatory instrument pertaining thereto (excluding with respect to (b) (4)); and

c. any outstanding Deliverables contemplated or materials purchased under this Project Agreement.

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

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

9.0 PUBLICATION POLICY

9.1 Publication of Clinical Data Related to the Trial

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

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

9.2 Publication of nonclinical Subject Data

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

10.0 SECURITY

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

The Attached Appendix 1 is hereby incorporated in this SOW.

11.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)

11.1 Associate Contractor Agreement (ACA)

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

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

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

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

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

(1) Maintenance of a close liaison and working relationship;

(2) Maintenance of a free and open information network with all Government-identified Associate Contractors;

(3) Delineation of detailed interface responsibilities;

(4) Entering into a written agreement with the other Associate Contractors setting forth the substance and procedures relating to the foregoing, and promptly providing the Agreements Officer/Procuring Contracting Officer with a copy of same; and,

(5) Receipt of proprietary information from the Associate Contractor and transmittal of Contractor proprietary information to the Associate Contractors subject to any applicable proprietary information exchange agreements between associate contractors when, in either case, those actions are necessary for the performance of either.

(d) In the event that the Contractor and the Associate Contractor are unable to agree upon any such interface matter of substance, or if the technical data identified is not provided as scheduled, Sanofi Pasteur shall promptly notify the Agreements Officer Representative and OTA Program Manager. The Government will determine the appropriate corrective action and will issue guidance to the affected Contractor.

(e) The Contractor agrees to insert in all subcontracts hereunder which require access to proprietary information belonging to the Associate Contractor, a provision which shall conform substantially to the language of this clause, including this paragraph (e).

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

(b) ACAs should include the following general information:

(1) Identify the associate contractors and their relationships.

(2) Identify the program involved and the relevant Government contracts of the associate contractors.

(3) Describe the associate contractor interfaces by general subject matter.

(4) Specify the categories of information to be exchanged or support to be provided.

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

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

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

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

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

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

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

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

12.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

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

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

AOR

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

Appendix 1: Clause for MCDC Consortium Other Transaction Authority Agreements

Standard Language OWS for Consortium OTA

Required MCDC Base Agreement Modifications

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

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

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

Information Security

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

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

Personnel Security

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

Supply Chain Resiliency Plan

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

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

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

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

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

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

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

Reports for critical items should include the following information:

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

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

Manufacturing Data Requirements:

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

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

- Stability information of bulk substance and/or finished product
- Shipment of bulk substance of final product
- Disposal of bulk substance or final product

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

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

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

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

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

Required SOW Language for Security Section

This project requires an OPSEC Plan and a Security Plan.

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

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

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

Security Requirements:

1. Facility Security Plan Description: As part of the partner facility's overall security program, the contractor shall submit a written security plan with their proposal to the Agreement Officer for review and approval by Operation Warp Speed security subject matter experts. The performance of work under the Project Agreement will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:	
Security Administration	• organization chart and responsibilities • written security risk assessment for site • threat levels with identification matrix (High, Medium, or Low) • enhanced security procedures during elevated threats • liaison procedures with law enforcement • annual employee security education and training program
Personnel Security	• policies and procedures • candidate recruitment process • background investigations process • employment suitability policy • employee access determination • rules of behavior/ conduct • termination procedures • non-disclosure agreements
Physical Security Policies and Procedures	• internal/external access control • protective services • identification/badging • employee and visitor access controls • parking areas and access control • perimeter fencing/barriers • product shipping, receiving and transport security procedures • facility security lighting • restricted areas • signage • intrusion detection systems • alarm monitoring/response • closed circuit television • product storage security • other control measures as identified
Information Security	• identification and marking of sensitive information • access control • storage of information • document control procedures • retention/ destruction requirements

Information Technology/Cyber Security Policies and Procedures	• intrusion detection and prevention systems • threat identification • employee training (initial and annual) • encryption systems • identification of sensitive information/media • password policy (max days 90) • lock screen time out policy (minimum time 20 minutes) • removable media policy • laptop policy • removal of IT assets for domestic/foreign travel • access control and determination • VPN procedures • WiFi and Bluetooth disabled when not in use • system document control • system backup • system disaster recovery • incident response • system audit procedures • property accountability
2. Site Security Master Plan Description: The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; IT Server Room; Product Storage Freezer/Room; and bio-containment laboratories.	
3. Site Threat / Vulnerability / Risk Assessment Description: The partner facility shall provide a written risk assessment for the facility addressing: criminal threat, including crime data; foreign/domestic terrorist threat; industrial espionage; insider threats; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies. The assessment should be updated annually.	
4. Physical Security Description:	
Closed Circuit Television (CCTV) Monitoring	a) Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored. b) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. c) Video recordings must be maintained for a minimum of 30 days. d) CCTV surveillance system must be on emergency power backup. e) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. f) Video recordings must be maintained for a minimum of 30 days. g) CCTV surveillance system must be on emergency power backup.
Facility Lighting	a) Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings. b) Lighting must have emergency power backup.

	c) Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.
Shipping and Receiving	a) Must have CCTV coverage and an electronic access control system. b) Must have procedures in place to control access and movement of drivers picking up or delivering shipments. c) Must identify drivers picking up Government products by government issued photo identification.
Access Control	a) Must have an electronic intrusion detection system with centralized monitoring. b) Responses to alarms must be immediate and documented in writing. c) Employ an electronic system (i.e., card key) to control access to areas where assets critical to the contract are located (facilities, laboratories, clean rooms, production facilities, warehouses, server rooms, records storage, etc.). d) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas. e) Must have a system that provides a historical log of all key access transactions and kept on record for a minimum 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.	

UNDEFINITIZED PROJECT ACTION

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

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

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

3. LIMITATIONS ON OBLIGATIONS:
   The Government will not obligate more than 50 percent of the NTE Price before definitization.

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

5. EXECUTION AND COMMENCEMENT OF WORK:
   Upon acceptance by both parties, the Contractor shall proceed with performance of the Statement of Work, including the purchase of any necessary materials.