AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 | 89

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00081	05-Aug-2020	SEE SCHEDULE	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than item 6)	CODE
US ARMY CONTRACTING COMMAND PHIPPS ROAD PICATINNY NJ 07806-5000	W15QKN	DCMA ATLANTA 2300 LAKE PARK DRIVE SUITE 300 SMYRNA GA 30080-4091	S1103A

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
ADVANCED TECHNOLOGY INTERNATIONAL ON BEHALF OF THE NCBDC 315 SIGMA DR SUMMERVILLE SC 29486-7790		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W15QKN-16-9-1002
	X	10B. DATED (SEE ITEM 13) 08-Apr-2016
CODE 1G3V8	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
IAW the terms and conditions of the OTA.

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: martins201688
See "SUMMARY OF CHANGES" for Modification Description.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
		(b) (6) / CONTRACTING OFFICER TEL: (b) (6) EMAIL: (b) (6)
15B. CONTRACTOR/OFFEROR (b) (6) (Signature of person authorized to sign)	15C. DATE SIGNED Dolan, Mica Sr. Vice President, Contracts and Procurement Aug 4 2020	16B. UNITED STATES OF AMERICA BY (b) (6) (Signature of Contracting Officer)
		16C. DATE SIGNED 05-Aug-2020

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION A - SOLICITATION/CONTRACT FORM

The following have been added by full text:
MOD DESCRIPTION - P00081

The purpose of this modification is to:

1) Award RPP 20-11, MCDC2011-004 (Janssen Pharmaceuticals, Inc.) via incorporation of the Terms and Conditions below:

2) Add incremental funding to the following project:

   RPP 20-11, PRE-20-11 (Janssen): $1,001,650,000.00 via CLIN 0058.

3) Incorporate an updated MCDC Award Tracker, listing the cost/fee and ceiling breakouts for each awarded project via MCDC Award Tracker P00081.

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

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

BETWEEN

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

AND

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

AND

THE MEDICAL DEFENSE CBRN DEFENSE CONSORTIUM
C/O ADVANCED TECHNOLOGY INTERNATIONAL
315 SIGMA DRIVE
SUMMERVILLE, SC 29486

CONCERNING

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

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

Project Identifier: MCDC2011-004

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

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

Funds Obligated: $1,001,650,000

Effective Date of Agreement:

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

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

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

Janssen Pharmaceuticals, Inc.

(b) (6)

DATE: 04 August 2020

U.S. Department of Defense

BY: (b) (6)

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

DATE: 05 August 2020

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

BY: (b) (6)

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

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RECITALS

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

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

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

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

Now therefore, the Parties agree as follows:

Article I. Scope of the Project Agreement

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

Section I.1 Introduction

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

Syrian hamsters. Additional preclinical results will be generated over the coming months, e.g. protection in Non-Human Primates ("NHP"). Clinical studies will start soon with the goal to demonstrate safety, immunogenicity and efficacy. Ad26.COV2.S will be manufactured on PER.C6® TetR cells and large-scale manufacturing will be needed to address the large demand for vaccination of large parts of the population.

The following efforts, while integral to the overall Ad26.COV2.S program, are outside the scope of this Project Agreement:

- Chemistry, Manufacturing, and Controls ("CMC") development, including manufacturing of Drug Substance ("DS") and Drug Product ("DP") and nonclinical and clinical development of Ad26.COV2.S, partially funded by BARDA OTA No. HHSO100201700018C;
- Large-scale manufacturing DS capacity established at a Janssen facility in Leiden, Netherlands, as well as with a Contracting Manufacturing Organization ("CMO"), Emergent BioSolutions, which is located in Rockville, MD;
- DP capacity established at Catalent in Bloomington, IN;
- Facility construction and modification, equipment purchase, qualification, and technical transfer activities to manufacture both DS and DP domestically;
- Preparation and submission of applications for an Emergency Use Authorization ("EUA") and Biologics License Application ("BLA"); and
- Monitoring, reporting, and healthcare worker, public education, and communications activities related to EUA distribution, which will be discussed and determined during the pre-EUA discussion period, as defined in applicable guidance documents.

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

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

Section I.2 Definitions

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

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

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

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

Agreements Officer's Representative ("AOR"): Reference back to Article I, Section 2 of the MCDC Base OTA No. W15QKN-16-9-1002.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Prototype Product: At least one of the 100 million Regimens of SARS-CoV-2 vaccine, Ad26.COV2.S recombinant resulting from the Prototype Project ("Ad26COV2.S").

Prototype Project: Janssen's demonstration of its capacity to perform large scale manufacturing domestically, utilizing the Janssen Manufacturing Capability of up to 100 million Regimens of Ad26.COV2.S.

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

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

Regimen: A "vaccine regimen" or "regimen" is either: two separate injections of $5x10^{10}$ viral injections (single/low doses/.25ml) or one single injection of $1x10^{11}$ viral particles (double/high dose/.5ml). If clinical trials support a different dosing or administration regimen, the Parties will discuss how to proceed and may agree to modify this Project Agreement in response.

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

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

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

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

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

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

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

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

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

Prototype Project. The scope of this Prototype Project is the demonstration by Janssen of the rapid, large scale supply and logistics capability to manufacture and deliver to the Government, 100M Regimens of the Ad26.COV2.S vaccine. Consistent with the Government's objectives under Operation Warp Speed ("OWS"), Janssen intends to employ its proprietary manufacturing technology and processes, in a manner compliant with applicable laws and regulations, including 21 CFR 210 and 211 and the Drug Supply Chain Security Act ("DSCSA") (to the extent required for COVID-19 medical countermeasures, as defined by relevant U.S. Food and Drug Administration ("FDA") guidance), to manufacture and deliver the Ad26.COV2.S vaccine. The successful provision of these Regimens shall establish the effectiveness of a technology capable of potentially providing immediate and long-term solutions to coronavirus infections. While preclinical and clinical activities are described in the Introduction section of this Statement of Work, the Parties acknowledge and agree that such activities are not related to the large-scale manufacturing demonstration and are out-of-scope for this Prototype Project.

This effort constitutes a prototype project because it will be used to evaluate the technical feasibility of completion of the Prototype Project during the ongoing COVID-19 pandemic and unprecedented threats to several components of the Prototype Project. In addition, this is a prototype project because Janssen will demonstrate and prove-out the at-scale, multi-lot proprietary manufacturing activities in order to assess the feasibility to support the necessary quantity of safe and effective regimens required for vaccination of the U.S. population. Successful completion of the Prototype Project will demonstrate Janssen's capability to rapidly manufacture product, which can be further scaled-up to meet mutually agreed to surge requirements with limited advance notification.

Milestones/Payments. One hundred million Regimens of Ad26.COV2.S vaccine will be provided by Janssen to the Government on a Firm Fixed Price ("FFP") per Regimen basis in accordance with the Milestone Payment Schedule. Due to variances in fill/finish yield, Janssen shall invoice for and the Government, through the CMF, shall pay for actual quantities delivered, at a rate of $10.00 per Regimen. Janssen shall use its reasonably diligent efforts to provide the Government the full 100M Regimens on or before the final delivery date. The Government will be under no obligation to receive or pay for any Regimens that are not made available for delivery according to the schedule defined in Table 1-1, except that (a) deliveries will be considered to be timely made according to the schedule to the extent that they are made up to 30 calendar days after the applicable delivery date, due to delays related to manufacturing, testing, or release, and (b) the Government will be obligated to accept and pay for Regimens that are not timely delivered by an initially applicable delivery date or within the alternative delivery windows identified in this paragraph, to the extent that any delay in delivery is solely attributable to an Excusable Delay Event as defined in Article IX, Section 4 of this Project Agreement. The Government will, at its discretion, have unilateral authority to extend future delivery dates before they have passed to the extent that any of the 100M Regimens are not expected to be delivered according to the schedule defined in Table 1-1; however, Janssen will be under no obligation to deliver Regimens after December 31, 2021, unless mutually agreed to by both Janssen and the Government. For the avoidance of doubt, to the extent there is a shortfall in the amount of Regimens delivered by any given delivery date, which is not

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

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

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

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

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

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

Table 1-1: Milestone Payment Schedule

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

Pricing Assumptions and Conditions

1) Short-term storage not to exceed 30 days and delivery to no more than 10 sites in the continental United States, are included in the $10/Regimen pricing.

2) At the discretion of the Government, Janssen shall provide the Government with up to twelve (12) months storage of up to 100M Regimens of Ad26.COV2.S (Milestone Number 7), (b) (4), (b) (2) The Government shall pay Janssen the full FFP amount, as identified in Table 1-1, distributed evenly across each month ordered for long-term storage capacity, with payment for each month due at the end of the applicable month. As applicable, Janssen will invoice the Government less per month for storage to the extent necessary to reflect Janssen storage vendor charges that are lower than expected for each month.

Section I.4 Scope of P00081 Modification

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

Current Good Manufacturing Practice ("cGMP") manufacturing, fully compliant with 21 CFR 210 and 211 subject to any guidance from, enforcement discretion exercised by, or formal waiver issued by the FDA in connection with COVID-19, of 100M Regimens of Ad26.COV2.S for distribution by the Government upon EUA under Section 564 of the Food, Drug, and Cosmetics ("FD&C") Act or a biologics licensure granted under Section 351(a) of the Public Health Service ("PHS") Act by the FDA, including:

- Final DP vaccine presentation will be subject to evaluation and discussion with the appropriate regulatory authorities under the BARDA OTA No. HHSO001201700018C. As such, the Parties understand and agree that the vaccine presentation may change during performance.

- Labeling of EUA Regimens using the date of manufacture, and not expiry, in order to ensure continuous supply of Ad26.COV2.S, recombinant vaccine is maintained and not disrupted when FDA licensure is received.

- Storage of up to 100 million Regimens of Ad26.COV2.S at Janssen or vendor facility.

- Compliance with the DSCSA Sections 581-585 of PL 113-54 (Nov 27, 2013), including product verification, serialization (serialization requirements need to be further evaluated and may impact timelines for delivery), traceability and detection and response requirements, unless exempted under DSCSA or other applicable legal exception, subject to any guidance from, enforcement discretion exercised by, or formal waiver issued by the FDA in connection with COVID-19.

- Shipping, if required, to up to ten (10) USG directed destinations.

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

Section I.5 Prototype Deliverables

Table 1-5: Prototype Deliverables

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

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

* Manufacturing Development Plan. Janssen will, in the level of detail and format that Janssen solely elects (*provided* such format provides a reasonable and industry-standard level of detail), describe the manufacturing process for the vaccine product to ensure conformity with §501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21 United States Code ("U.S.C.") §351 (a)(2)(B)), regarding GMP. This plan shall describe as such information becomes available to Janssen, but is not limited to, planned or completed drug substance studies; list of excipients and information to support the safety of excipients that, when appropriate, shall be cross-referenced; drug product and formulation development summary from initial concept through final design; physicochemical and biological properties; manufacturing process development and validation program documents; container closure system documents; microbiological attributes documents and plans; compatibility documents (*e.g.*, precipitation); assay development and validation, stability plan; and any associated risks.

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

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

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

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

Section I.6 Follow-on Production

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

Article II. Term and Termination

Section II.1 Term

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

Section II.2 Termination

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

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

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

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

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

Section II.3 Extension of Term

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

Article III. Project Management, Modifications, and Administration

Section III.1 Management and Modifications

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

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

b. **Project Management.** Janssen and the Government will each designate an individual responsible for facilitating the communications, reporting, and

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

c. **Project Reviews.** Janssen and the Government will hold periodic project review meetings as determined by the Janssen Project Manager and AOR, however, these meetings shall not occur more frequently than every fourteen (14) calendar days.

d. **Reviews Resulting in Modifications.** During the performance of this Project Agreement, as described above, it may be necessary to modify the Statement of Work or delivery timeframes. No communications, whether oral or in writing, that purport to change this Project Agreement are valid unless a modification is issued by the AO. The Parties hereby agree that any mutually agreed upon written request for modification shall be executed in an expedited timeframe.

e. **Bilateral Modifications.** Janssen or the Government may propose modifications to this Project Agreement. A modification that materially changes the obligations of either the Government or Janssen must be in writing and signed by the AO and Janssen's authorized official. Janssen's requests for modifications shall detail the technical and chronological impact of the proposed change on the Statement of Work or delivery timeframes.

f. **Unilateral Modifications.** The AO may ONLY issue minor or administrative modifications, which do not change the obligations of Janssen in any adverse manner, such as changes to the paying office or appropriations data, or changes to Government personnel identified in the Project Agreement. Unilateral modifications will only be signed by the AO.

Section III.2 Project Agreement Administration

Government Points of Contact:

AO

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

AOR

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

Janssen Points of Contact:

CLM

NAME:
MAILING ADDRESS:
EMAIL:
PHONE:

(will be provided within 30 calendar days after award)

PM

NAME:
MAILING ADDRESS:
EMAIL:
PHONE:

(will be provided within 30 calendar days after award)

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

Article IV. "PREP ACT" Coverage

In accordance with the Public Readiness and Emergency Preparedness Act ("PREP Act"), Pub. L. No. 109-148, Division C, Section 2, as amended (codified at 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e), as well as the Secretary of Health and Human Service's ("HHS") Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020, effective Feb. 4, 2020), and amended on April 15, 2020, 85 Fed. Reg. 21012, and on June 8, 2020, 85 Fed. Reg. 34740 (together, the "Prep Act Declaration"):

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

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

(iii) Janssen is a "Covered Person" per Section V of the PREP Act Declaration.

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

The Government may not use, or authorize the use of, any products or materials provided under this Project Agreement, unless such use occurs in the United States (or a U.S. territory where U.S. law applies such as embassies, military installations and NATO installations) and is protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act Declaration of equal or greater scope. Any use where the application of the PREP Act is in question will be discussed with Janssen prior to use and, if the parties disagree on such use, the dispute will be resolved according to Article VI, "Disputes."

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

Article V. Obligation and Payment

Section V.1 Limitation of Liability

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

Section V.2 Fixed Price Payment Method

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

a. contains the date of invoice and the base Agreement number and Project Agreement number;

b. identifies any associated technical milestones and the progress toward completion of each milestone; and

c. lists the price contained in each Project Agreement.

Section V.3 Accounting System Requirements

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

Section V.4 Payments and Payment Instructions

a. The Parties agree that fixed payments will be made for delivery of product or storage. These payments reflect the value received by the Government toward the accomplishment of the goals of this Project Agreement.

b. Janssen shall submit an original invoice as described in Article V, Section 2, above, via (b) (4) [redacted] Payment terms are NET 30 days after CMF's receipt of an invoice that meets the conditions of Article V, Section 2 above.

c. In accordance with Article XII, herein, the Government shall inspect, accept or reject the work as promptly as practicable after submission or completion, unless otherwise specified in this Project Agreement/Statement of Work. Government failure to inspect, accept or reject the work shall not relieve Janssen from responsibility, nor impose liability on the Government, for nonconforming work. Work is nonconforming when it is defective in material or workmanship or is otherwise not in conformity with contract requirements. The remedy for nonconforming is rework by Janssen within reasonably revised timelines.

d. The Parties hereby agree that reasonable delays in performance of this Project Agreement/Statement of Work shall not be considered nonconforming work, as defined above. The Parties hereby further agree that Janssen has provided timelines based on its best estimates in accordance with the Government's accelerated timeframes and that the nature of vaccine production/manufacturing is inherently complex and in order to ensure appropriate quality, safety and efficacy standards are met, some delays are unavoidable and these delays will be addressed by the Parties under the Governance structure of Article III of this Project Agreement/Statement of Work, as the circumstances dictate at that time. Each delivery identified in Table 1-1 will be made independent of the other deliveries, and a failure to make one or more deliveries will not impact the Parties' obligations with respect to the other deliveries as long as Janssen continues to make reasonably diligent efforts to make each delivery under this Project Agreement.

Section V.5 Comptroller General Access to Records

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

Article VI. Disputes

A. General

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

B. Dispute Resolution Procedures

1. Any claim or dispute between the Government and Janssen concerning questions of fact or law arising from or in connection with this Project Agreement, and, whether or not involving an alleged breach of this Project Agreement, shall be raised and resolved under this Article.

2. Whenever legal disputes or claims arise, the Parties shall attempt to resolve the issue(s) by discussion and come to mutual agreement on a resolution as soon as practicable. In no event shall a dispute, disagreement or misunderstanding that arose more than three (3) months prior to the notification made under sub-section B.3 of this article constitute the basis for relief under this article unless one level above the AO, in the interests of justice, waives this requirement.

3. Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party (through the AO or Janssen's POC, as the case may be) in writing of the relevant facts, identifying unresolved issues, and specifying the clarification or remedy sought. Within five (5) working days after providing notice to the other Party, the aggrieved Party may, in writing, request a joint decision by the ACC-NJ Division Chief for Emerging Technologies and senior executive appointed by Janssen. The other Party shall submit a written response on the matter(s) in dispute within thirty (30) calendar days after being notified that a decision has been requested. The Division Chief and the Recipient

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

4. In the absence of a joint decision, upon written request to the ACC-NJ Associate Director made within thirty (30) calendar days of the expiration of the time for a decision under sub-section B.3 above, the dispute shall be further reviewed. The Associate Director may elect to conduct this review personally or through a designee or jointly with a senior executive appointed by Janssen. Following the review, the Associate Director or designee will resolve the issue(s) and notify the Parties in writing. This decision may be appealed to any federal court of competent jurisdiction.

5. Notwithstanding any other provisions of this Article, the Parties agree that Janssen shall have the right to pursue any contract dispute arising under this Project Agreement in any federal court of competent jurisdiction, including the appropriate Court of Appeals, or the Supreme Court, at any time without any administrative exhaustion requirements, and the timing requirements described above will not limit any claim in such tribunals. For the avoidance of doubt, the Parties agree that this Project Agreement satisfies all elements of an agreement.

C. Limitation of Damages

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

Article VII. Confidential Information

Section VII.1 Authorized Disclosure

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

Section VII.2Exclusions

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

Section VII.3Term

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

Article VIII. Publication and Academic Rights

Section VIII.1 Use of Information.

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

Section VIII.2 Publication or Public Disclosure of Data

Review and Approval of Data for Public Release.

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

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

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

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

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

Article IX. Patent Rights

Section IX.1 Background Intellectual Property Disclosures

Janssen asserts full title to all background intellectual property relevant to its performance of this statement of work and listed at Attachment 1. Janssen hereby conveys a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States to the "Licensed Patents" throughout the world for the prevention, diagnosis and treatment of COVID-19 caused by Severe Respiratory Syndrome-Coronavirus-2 (SARS CoV-2). "Licensed Patents" means US Provisional Patent Application Serial Nos. (b) (4) [redacted] as well as any and all patent applications and patents (including any counterparts, PCT's, national stage applications, divisionals, continuations, or the like thereof, and any extensions thereof), wherever filed in the world, that claim priority to US Patent Application Serial No. (b) (4) [redacted] The Parties agree that nothing in this Project Agreement will otherwise alter the existing patent rights of the Parties unless expressly agreed upon.

Section IX.2 Allocation of Principle Rights

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

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

a. Janssen shall disclose each Subject Invention to the Government within two (2) months of the Subject Invention being disclosed in writing to the person responsible for Janssen patent matters. The Subject Invention shall be disclosed in writing to the Government, via appropriate filings in the iEdison system or its replacement/alternative system, with a copy of said reporting being sent to JPEO-CBRND. Further, Janssen shall elect in writing whether or not to retain title to any such invention by notifying the Government within 6 months of disclosure to the Government.

b. Where publication, sale, or public use has initiated the one (1)-year statutory period wherein valid patent protection can still be obtained in the United States,

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

c. If electing title, Janssen will file its initial patent application on a Subject Invention to which it elects to retain title within one year after election of title, or, if earlier, prior to the end of the statutory period wherein valid patent protection can be obtained in the United States after a publication, or sale, or public use.

d. Foreign Patent Filing Requirements: Janssen may elect to file corresponding patent applications in additional countries outside the U.S. (including but not limited to the European Patent Office and the Patent Cooperation Treaty) at its discretion. To enable the Government to protect patent rights in Subject Inventions in all potential countries, Janssen shall inform the Government of which countries Janssen shall NOT file patents applications in for all elected Subject Inventions at least 3 months prior to the filing deadline therein (e.g., in PCT national stage applications, at least 3 months prior to the PCT national stage filing deadline). Janssen understands that, in case the Government decides to file in a particular country following a notice provided under the preceding sentence, all ownership and interest in Subject Inventions in said countries (where Janssen shall not file patent applications in) are thereby automatically conveyed to the Government, and Janssen agrees to timely execute any documentation required to effectuate this conveyance, so as to enable the Government to perfect patent filing in said countries, always subject to the license described in Article IX, Section 5(a).

e. If Janssen does not elect title via the process described above, or determines that neither it nor its designee intends to file any patent applications on a Subject Invention, Janssen shall notify the Government, in writing, within 6 months of disclosure of such Subject Invention to the Government. Janssen agrees, in such case, to permit the Government to elect title to said Subject Invention, and thereby have full rights and ownership therein, at least 3 months PRIOR to the end of the one (1)-year statutory period wherein valid patent protection can still be obtained in the United States after any publication, sale, or public use.

f. In addition to the reporting required above, Janssen shall identify Subject Inventions in an annual report and the final report, which shall be in sufficiently complete technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the Subject Invention.

g. Neither Party will publicly disclose any Subject Invention until a patent application describing the Subject Invention is filed, or a reasonable period of time has passed in the event that a patent application is not filed, in order to protect the patentability of the invention pursuant to 35 U.S.C. § 205.

Section IX.4 Conditions When the Government May Obtain Title

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

a. Of any Subject Invention, if Janssen fails to disclose the Subject Invention or elects not to retain title to the Subject Invention within the times specified in Article IX, Section 3(a) and (b), the Government may request title for a period of up to 60 calendar days after learning of the failure of Janssen to disclose within the specified times. For the avoidance of doubt, disclosure under this paragraph shall be deemed to have occurred at the time of Janssen's notification to JPEO-CBRND of a Subject Invention regardless of whether such disclosure meets the standards set forth in Article IX, Section 3(a) above.

b. Of a patent application or patent that claims a Subject Invention, as the case may be, in any country in which Janssen decides not to continue the prosecution of such patent application, or to pay the maintenance fees on or defend in reexamination or opposition proceedings such a patent.

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

a. Janssen shall retain a nonexclusive, royalty-free license throughout the world in each Subject Invention to which JPEO-CBRND obtains title under Article IX, Section 8. The Janssen license extends to the Janssen's Affiliates, and includes the right to grant licenses of the same scope to the extent that Janssen was legally obligated to do so at the time the Project Agreement was awarded or at the time of the Subject Invention was invented. The license is transferable only with the approval of JPEO-CBRND, except when transferred to the successor of that part of the business to which the Subject Invention pertains. JPEO-CBRND approval for license transfer shall not be unreasonably withheld.

b. The Janssen license may be revoked or modified by the Government to the extent necessary to achieve expeditious Practical Application of the Subject Invention pursuant to an application for an exclusive or non-exclusive license submitted consistent with appropriate provisions at 37 CFR Part 404.

c. Before modification of the license, JPEO-CBRND shall furnish Janssen a written notice of its intention to revoke or modify the license, and Janssen shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be modified.

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

a. Janssen agrees to execute or to have executed and promptly deliver to JPEO-CBRND all instruments necessary to (i) establish or confirm the rights JPEO-CBRND has throughout the world in those Subject Inventions to which Janssen elects to retain title, and (ii) convey title to JPEO-CBRND when requested under Section 4 of this Article IX and to enable JPEO-CBRND to obtain patent protection throughout the world in that Subject Invention.

b. Janssen agrees to require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing, to personnel identified as responsible for the administration of patent matters and in a format suggested by Janssen, each Subject Invention in order that Janssen can comply with the disclosure provisions of Section 3 of this Article IX. Janssen shall instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting Subject Inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

c. Janssen shall notify JPEO-CBRND of any decisions not to continue the prosecution of a patent application claiming a Subject Invention, pay maintenance fees on a patent claiming a Subject Invention, or defend in a reexamination or opposition proceedings on a patent claiming a Subject Invention, in any country, not less than sixty (60) calendar days before the expiration of the response period required by the relevant patent office.

d. Janssen shall include, within the specification of any United States patent application and any patent issuing thereon claiming a Subject Invention, the following statement: "This invention was made with Government support under Agreement [W15QKN-19-6-1002, 2011-004], awarded by JPEO-CBRND. JPEO-CBRND has certain rights in the invention."

Section IX.7 Reporting on Utilization of Subject Inventions

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

b. All required reporting shall be submitted to the AO and AOR.

c. Where the Subject Invention is a drug or a vaccine, or a method of manufacturing, administering or using a drug or vaccine, Practical Application in view of the March-in Rights in Article IX, Section 8 below is achieved with respect to:

   i. such drug or vaccine, if a Phase IIa clinical study is completed that studies such drug or vaccine; or

   ii. such method of use, if the method of use is employed in manufacture, administration or use of such drug or vaccine in connection with a Phase IIa clinical study.

d. Failure to complete a Phase IIa clinical study does not per se constitute a failure to achieve Practical Application.

Section IX.8 March-in Rights

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

a. Such action is necessary because Janssen or assignee has not taken steps (or is not expected to take within a reasonable time), consistent with the intent of this Project Agreement, to achieve Practical Application of the Subject Invention; or

b. Such action is necessary to alleviate the following urgent health or safety needs not reasonably satisfied by the contractor that affect the United States and that are not reasonably satisfied by Janssen, assignee, or their licensees:

   i. declaration for Public Health Emergency by the Secretary of the Government;

   ii. determination that there is a significant potential for a public Health emergency that has a significant potential to affect the national security or public health of U.S. citizens as determined by the Secretary of the Government; or

   iii. declaration by WHO Director General of a public health emergency of

international concern.

c. Where the circumstances described in Article IX, Section 8(a) and or (b) are met, Janssen will act promptly to negotiate in good faith with the responsible US-based third party a non-exclusive license on terms that are reasonable under the circumstances under the SI Intellectual Property Rights it controls at the time to make, have made, use, sell, offer for sale and import the relevant Subject Invention in the Field to the extent necessary to alleviate the public health emergency in the United States.

Section IX.9 Background Information

Janssen shall retain the entire right, title, and interest throughout the world to each such Invention and Patent that Janssen has brought to the Prototype Project issued under this Project Agreement/Statement of Work and the Government shall not have any rights under this Project Agreement/Statement of Work to such Inventions and Patents unless identified herein. Attachment 1 to the Project Agreement contains non-exhaustive overview of Janssen's Background Patents, patent applications and Inventions at the Effective Date. Table 10-1 in Article X "Data Rights" provides a non-exhaustive overview of Data Rights, information and Technical Data that Janssen will bring to the Project Agreement at the Effective Date. The Government shall have no rights to these Background Inventions, Patents, information and Technical Data and any further Background Inventions, Patents, information and Technical Data identified during the Term of the Project Agreement or afterwards.

Article X. Data Rights

Table 10-1: Janssen Background Information, Data Rights and Technical Data

Technical Data to be Furnished with Restrictions	***Basis for Assertion***	***Asserted Rights Category***	***Name of Person Asserting Restrictions***
(b) (4) [redacted]	[redacted]	*A*	*Janssen*
(b) (4) [redacted]	[redacted]	*A*	*Janssen*
(b) (4) [redacted]	[redacted]	*A*	*Janssen*
(b) (4) [redacted]	[redacted]	*A*	*Janssen*
(b) (4) [redacted]	[redacted]	*A*	*Janssen*

Technical Data to be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Person Asserting Restrictions
(b) (4) [redacted]	[redacted]	A	Janssen
(b) (4) [redacted]	[redacted]	A	Janssen
(b) (4) [redacted]	[redacted]	A	Janssen
(b) (4) [redacted]	[redacted]	A	Janssen
(b) (4) [redacted]	[redacted]	A	Janssen
(b) (4) [redacted]	[redacted]	A	Janssen
(b) (4) [redacted]	[redacted]	A	Janssen
(b) (4) [redacted]	[redacted]	A	Janssen

Section X.1 Data Categories

Article XI of the Agreement, is hereby superseded by the following terms and conditions:

There are two (2) categories of Data or other information established under this Project Agreement as listed below.

a. Category A is Data or other information to which Janssen retains all rights. Category A Data shall include, but not be limited to:

   i. Data as defined in the Project Agreement, background (i.e., pre-existing or generated outside the scope of this Project Agreement) information and Technical Data identified in Table 10-1 and Attachment 1 (background Patents, patent applications and Inventions), and any designs or other material provided by Janssen for this Project Agreement which was not developed in the performance of work under this project, and to which Janssen retains rights.

   ii. The Parties hereby mutually agree that any information developed outside of this Project Agreement whether or not developed with any Government funding in whole or in part under a Government agreement, contract or subcontract shall have the rights negotiated under such prior agreement, contract or subcontract; the Government shall get no additional rights in such information.

b. Category B is any Data developed exclusively with Government funds under this Project Agreement.

   i. The Government will have Government Purpose Rights in Data developed exclusively with Government funds under this Project Agreement.

   ii. The Government shall have unlimited rights in Data:

      (a) Otherwise publicly available or that has been released or disclosed by Janssen without restrictions on further use, release or disclosure, other than a release or disclosure resulting from the sale, transfer, or other assignment of interest in the Data to another party or the sale or transfer of some or all of a business entity or its assets to another party;

      (b) Data in which the Government has obtained unlimited rights under another Government contract or as a result of negotiations; or

      (c) Data furnished to the Government, under this or any other

Government contract or subcontract thereunder, with—

1. government purpose rights or limited rights and the restrictive condition(s) has/have expired; or

2. Government purpose rights and Janssen's exclusive right to use such Data for commercial purposes under such contract or subcontract has expired.

iii. However, any Data or other information developed outside of this OTA whether or not developed with any Government funding in whole or in part under a Government agreement, contract or subcontract shall have the rights negotiated under such prior agreement, contract or subcontract; the Government shall get no additional rights in such Data or other information.

Section X.2 Allocation of Principle Rights

a. The Government shall have no rights to Category A Data or other information, but shall have rights to Deliverables as described in Table I-5.

b. The Government will receive Government Purpose Rights in Data or other information exclusively funded by the Government and otherwise Limited Rights in any data delivered in the performance of the SOW. To the extent that the Parties mutually agree that there will be Data subject to Government Purpose Rights, Data subject to Government Purpose Rights may only be shared with parties outside the Government when such parties are subject to the non-disclosure agreement at DFARS 227.7103-7 with respect to the data or are receiving the data under a Government contract subject to DFARS 252.227-7025. Any delivered Data or other information which is part of a patent application claiming a Subject Invention will be subject to the disclosure and release restrictions set forth in Article X, Section 2 of this Project Agreement.

c. Data or other information in any document which is a part of a patent application that would disclose a Subject Invention will be subject to Limited Rights until publication of patent application in accordance with Article X of this Project Agreement/Statement of Work.

d. Janssen agrees to retain and maintain in good condition all Data necessary to achieve Practical Application of any Subject Invention in accordance with the Janssen's established record retention practices. In the event of exercise of the Government's March-in Rights as set forth under Article X, Janssen agrees, upon written request and with adequate additional support from the Government, as mutually agreed between the Parties, to deliver Data necessary to achieve Practical Application within one-hundred and twenty (120) calendar days from the date of the written request.

e. Janssen's right to use Data is not restricted and includes the right under Janssen's established business policies to make public research data (especially human research data) by publication in the scientific literature, by making trial protocols, trial results summaries, and clinical studies reports publicly available, and by making trial patient-level data available for third-party analysis. The Government agrees that the materials, if any, being developed under this Project Agreement/Statement of Work are being developed for both civilian and military applications.

Section X.3 Identification and Disposition of Data

Janssen shall keep copies of all Data required by the FDA relevant to this Project Agreement for the time specified by the FDA and provide such Data to AO. The Government reserves the right to review any other Data determined by the Government to be relevant to this Project Agreement/Statement of Work subject to Limited Rights.

a. Marking of Data

Pursuant to section A above, any Data delivered under this Project Agreement/Statement of Work that is subject to Government Purpose Rights shall be marked with the following legend or similar:

"*GOVERNMENT PURPOSE RIGHTS: The Government's right to use, modify, reproduce, perform, display or disclose this Data is restricted by P00081 Modification to the MCDC OTA No.* W15QKN-16-9-1002 *between the Government, ATI and Janssen, and those restrictions do not permit disclosure to any party outside the Government unless such disclosure is for government purposes and not facilitating commercial sale beyond the government. Any reproduction of this Data or portions thereof must be marked with this legend.*"

b. Pursuant to section A above, any Data delivered under this Project Agreement/Statement of Work that is subject to Limited Rights shall be marked with the following legend or similar:

"LIMITED RIGHTS: The Government's right to use, modify, reproduce, perform, display or disclose this Data is restricted by P00081 Modification to the MCDC OTA No. W15QKN-16-9-1002 *between the Government, ATI and Janssen, and those restrictions do not permit disclosure to any party outside the Government without prior agreement of Recipient. Any reproduction of this Data or portions thereof must be marked with this legend."*

Article XI. Export Control

This term/condition is not applicable to this Project Agreement.

Article XII. Government Furnished Property

It is not anticipated that any Government furnished equipment, materials, information, or other property will be provided to Janssen nor will Janssen procure any property intended to be Government furnished under this Project Agreement.

Article XIII. Civil Rights Act

Reference back to Article XIV of the MCDC Base OTA No. W15QKN-16-9-1002.

Article XIV. Small Business Affiliation

This term/condition is not applicable to this Project Agreement.

Article XV. Antitrust

This term/condition is not applicable to this Project Agreement.

Article XVI. Security and Operations Security ("OPSEC")

To the extent that Janssen does not meet any requirements in this Article XVI or Attachment 2 at the time of award of this Project Agreement, Janssen will notify the Government and will have 180 days to work with the Government to develop a plan to which Parties agree to address such requirements, Janssen will be entitled to an equitable adjustment to account for costs associated with implementing the plan agreed to by the Parties.

The OPSEC provisions included in Attachment 2 are hereby incorporated into this Project Agreement.

All PAH shall comply with DFARS 252.204-7012 (Oct 2016): Safeguarding Covered Defense Information and Cyber Incident Reporting when applicable.

Covered Defense Information ("CDI") will be identified at the Project Agreement level. The MCDC Member shall comply with DFARS 252.204-7012 (Oct 2016): Safeguarding Covered Defense Information and Cyber Incident Reporting, which includes implementing on its covered contractor information systems the security requirements specified by DFARS 252.204-7012. Nothing in this paragraph shall be interpreted to foreclose the MCDC Member's right to seek alternate means of complying with the security requirements in National Institute of Standards and Technology ("NIST") Special Publication (SP) 800-171 (as contemplated in DFARS 252.204-7008 (Compliance with

Safeguarding Covered Defense Information Controls) (Oct 2016) and DFARS 252.204-7012 (Safeguarding Covered Defense Information and Cyber Incident Reporting (Oct 2016)).

(1) For all Project Agreements, the following statement shall be flowed to the MCDC member entities unless otherwise stated within the Project Agreements.

a) Classification guidance for requirement - "The security level for this agreement is UNCLASSIFIED."

Article XVII. Safety

This term/condition is not applicable to this Project Agreement.

Article XVIII. Representations and Warranties

Reference back to Article XIX of the MCDC Base OTA No. W15QKN-16-9-1002.

Section XVIII.1 Representations and Warranties of All Parties

Each Party to this Project Agreement represents and warrants to the other Parties that (1) it is free to enter into this Agreement; (2) in so doing, it will not violate any other agreement to which it is a party; and (3) it has taken all action necessary to authorize the execution and delivery of this Project Agreement and the performance of its obligations under this Project Agreement.

Section XVIII.2 Limitations

Except as expressly provided herein, no Party to this Project Agreement makes any warranty, express or implied, either in fact or by operation of law, by statute or otherwise, relating to (1) any research conducted under this Project Agreement, or (2) any invention conceived and/or reduced to practice under this Project Agreement, or (3) any other intellectual property developed under this Project Agreement or noninfringement, and EACH PARTY TO THIS PROJECT AGREEMENT SPECIFICALLY DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY OR WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.

Article XIX. General Provisions

Section XIX.1 Fees

This term/condition is Not Applicable to this Project.

Section XIX.2 Waiver

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

Section XIX.3 Section Headings

Reference back to Article XXI, Section 3 of the MCDC Base OTA No. W15QKN-16-9-1002.

Section XIX.4 Severability

If any provision of this Project Agreement, or the application of any such provision to any person or set of circumstances, is determined to be invalid, unlawful, void or unenforceable to any extent, the remainder of this Project Agreement, and the application of such provision to persons or circumstances other than those as to which it is determined to be invalid, unlawful, void or unenforceable, will not be impaired or otherwise affected and will continue to be valid and enforceable to the fullest extent permitted by law.

Section XIX.5 Excusable Delay

Neither Party will be liable to the other Party for failure or delay in performing its obligations hereunder if such failure or delay arises from circumstances beyond the control and without the fault or negligence of the Party (an "Excusable Delay Event"). Examples of such circumstances are: authorized acts of the Government in its sovereign capacity (or failure to take reasonably expected acts), war, insurrection, freight embargos, fire, flood, or strikes. The Party asserting Excusable Delay as an excuse must take reasonable steps to minimize delay or damages caused by unforeseeable events. The Government may not identify any aspect of the COVID-19 pandemic as an Excusable Delay Event relieving it of its responsibilities under this Project Agreement.

Section XIX.6 Regulatory Rights

a. The Parties understand and hereby acknowledge that BARDA OTA No. HHSO100201700018C ("BARDA OTA") governs Janssen's responsibilities and obligations with regards to IND activities regarding Janssen's Ad26.COV2.S vaccine, specifically, Work Package 6.14, "Regulatory Support" of the BARDA OTA. Under the BARDA OTA, Janssen leads regulatory activities with the FDA. Janssen manages all regulatory communications, documentation, and submissions with health authorities. Janssen provides BARDA with all communications and summaries thereof, both formal and informal, to or from FDA regarding the Investigational New Drug ("IND") activities regarding Janssen's Ad26.COV2.S vaccine and will invite the BARDA/JPEO-CBRND representatives to participate in any formal meetings between FDA and Janssen. Additionally, for this Project Agreement, Janssen will authorize BARDA to share information with the United States Department of Defense, JPEO-CBRND, as BARDA deems appropriate, in accordance with the Data Rights requirements of BARDA OTA No. HHSO100201700018C.

b. The Parties also understand that PL-115-92 allows the DoD to request, and FDA to provide, assistance to expedite development and the FDA's review of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. Janssen recognizes that only the DoD is authorized to invoke PL-115-92. If Janssen, the DoD, and BARDA agree that the circumstances exist under the BARDA OTA to warrant DoD's involvement, Janssen and BARDA may request DoD to utilize its authority under PL-115-92 to engage the FDA.

   If DoD, in its sole discretion, determines that it will engage with the FDA, the Parties agree that DoD will only invoke this authority in order to assist or facilitate Janssen in obtaining the necessary FDA approvals or authorizations. Notwithstanding any other provision in this Project Agreement, the BARDA OTA, or PL-115-92, the Parties agree that DoD shall not use its authority to become a "sponsor," co-sponsor, or "applicant" as defined in the regulations cited in this Article. Further, the Parties hereby agree that any information provided to DoD by Janssen, to facilitate with the FDA under PL-115-92, will be provided with Limited Rights pursuant to the BARDA OTA.

c. *Rights of Reference.* In the event that all of the conditions described in Article 19, Section 7(1) are met, Janssen will grant the Government a right of reference to any regulatory application submitted to the FDA in support of this Project Agreement/Statement of Work. Separately, upon the DoD's request, Janssen will grant the DoD a right of reference to any regulatory application submitted to the FDA in support of this Project Agreement/Statement of Work for the DoD's regulatory filings involving (a) the use of a product to treat or prevent COVID-19 or (b) one of the material threats identified in Attachment 3, in each case for which the DoD is identified as the filing sponsor. DoD may request a

right of reference to additional material threats identified by the Government under Section 319F-2(c)(2)(A)(ii) of the Public Health Service Act, and Janssen may consent to provide such a right of reference with the agreement that its consent will not be unreasonably withheld. For clarity, the rights of reference identified in this paragraph will only authorize the FDA to cross-reference regulatory applications and will not provide the DoD or any other party with a right to access or review any such applications or information included in such applications.

Section XIX.7 Failure to Provide Prototype Product

1. In recognition of the Government's need to provide sufficient quantities of a safe and effective Prototype Product to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the Prototype Product to meet the needs of the public health or national security when the following conditions are met:

a. Janssen gives written notice (which it hereby agrees to do) to the Government no later than 15 business days following:

i. except as permitted under Article I, Section 3 or in connection with a termination of this Project Agreement under Article II, Section 2 above, any formal management decision to terminate manufacturing of the Prototype Product prior to delivery of 100 million Regimens of the Prototype Product to USG; or

ii. except as permitted under Article I, Section 3 or in connection with a termination of this Project Agreement under Article II, Section 2 above, any formal management decision to discontinue sale of the Prototype Product to the Government prior to delivery of 100 million Regimens of the Prototype Product to USG; or

iii. any filing that anticipates Federal bankruptcy protection of Janssen prior to the delivery of 100 million Regimens of the Prototype Product; and

b. Janssen

i. is authorized to supply the Prototype Product under an Emergency Use Authorization under §564 of the FD&C Act; or

ii. has an FDA approval to market the Prototype Product in the U.S. under the provisions of §351(a) of the Public Health Service Act (PHSA).

2. If both conditions listed in subsection (1) occur, Janssen, during the emergency pandemic for COVID-19 issued under §319 of the PHSA, upon the written request of the Government, will act promptly to license a Third-Party Licensee all Janssen Prototype Product Rights on reasonable terms for the continuation and/or initiation of manufacturing of the Prototype Project at the Government's expense.

3. This Article will survive the acquisition or merger of Janssen with a third party. This Article will survive the expiration of this Project Agreement unless the Project Agreement was terminated under Article II, Section 2(a).

Section XIX.8 Radioactive Materials

This term/condition is not applicable to this Project Agreement.

Section XIX.9 Recombinant DNA

This term/condition is not applicable to this Project Agreement.

Section XIX.10 Required Compliance for Use of Laboratory Animals

This term/condition is not applicable to this Project Agreement.

Section XIX.11 Required Compliance for Use of Human Subjects

This term/condition is not applicable to this Project Agreement.

Section XIX.12 Required Compliance for use of Human Anatomical Substances

This term/condition is not applicable to this Project Agreement.

Section XIX.13 Compliance with Good Manufacturing Processes

The cGMP (21 CFR 210-211) will be the standard applied for manufacturing, processing and packing of any products to be administered to human subjects under this Project Agreement subject to any applicable guidance from, or enforcement discretion exercised by, the FDA in connection with COVID-19 subject to any applicable guidance from, or enforcement discretion exercised by, the FDA in connection with COVID-19.

If at any time during the life of this contract, the Recipient fails to comply with cGMP in the manufacturing, processing and packaging of the products subject to the exception noted above and such failure results in a material adverse effect on the safety, purity or potency of the products (a material failure) as identified by Center for Biologics Evaluation and Research and Center for Drug Evaluation and Research, the Recipient shall have thirty (30) calendar days from the time such

material failure is identified to cure such material failure. If the Recipient fails to take such an action within the thirty (30) calendar day period, then the contract may be terminated.

The Recipient agrees to comply with cGMP guidelines (21 CFR Parts 210-211,600) for manufacturing, processing and packing of drugs, chemicals, biological, and reagents subject to any applicable guidance from, or enforcement discretion exercised by, the FDA in connection with COVID-19.

The Recipient agrees to advise the AO and AOR promptly of any relocation of their prime manufacturing facility or the relocation of any sub consortium's facility during the term or this Project Agreement. The Recipient also agrees to advise the AO and AOR immediately if at any time during the term of this Project Agreement, the items under this OTA fail to comply with cGMP guidelines and/or the facility receives a negative FDA Quality Assurance Evaluation (Form 483).

Section XIX.14 Registration with Select Agent Program

This term/condition is not applicable to this Project Agreement.

Section XIX.15 Duty Free Entry

Reference back to Article XXI, Section 14 of the MCDC Base OTA No. W15QKN-16-9-1002.

Article XX. Assignment of Agency

Neither this Project Agreement nor any rights or obligations of any Party hereunder shall be assigned or otherwise transferred by any Party without the prior written consent of the other Parties, except that Janssen may assign to an Affiliate or to a third party to whom it transfers the portion of its business applicable to this Project Agreement, in each case, without prior written consent.

Article XXI. Order of Precedence

In the event of any inconsistency between the general terms of this Project Agreement and the Agreement, the inconsistency shall be resolved by giving precedence in the following order: (1) the Scope/Statement of Work of the Project Agreement; (2) Attachments to the Project Agreement; (3) the Project Agreement terms and conditions; (4)documentation (including but not limited to Janssen's proposal selected for funding by the Government); (5) the general terms and conditions of the Agreement. In any event, specifically negotiated Project Agreement terms will govern over general terms of the Agreement.

The Parties mutually agree that any terms and conditions that have been identified with the following statement "**This term/condition is Not Applicable to this Project**

Agreement" shall have no effect and are expressly excluded from the MCDC Base OTA No. W15QKN-16-9-1002. The terms and conditions in the MCDC Base OTA No. W15QKN-16-9-1002, that have been changed within this Project Agreement, are hereby superseded by the language in this Project Agreement. As such, those sections from the MCDC Base OTA No. W15QKN-16-9-1002 shall no longer remain operative with regards to this Project Agreement/Statement of Work. Any terms and conditions that have not been changed or have not been identified with the above statement remain unchanged and in full force and effect.

Article XXII. Execution

This Project Agreement constitutes the entire agreement of the Parties and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions among the Parties, whether oral or written, with respect to the subject matter hereof. This Project Agreement may be revised only by written consent of Janssen and the AO. This Project Agreement, or modifications thereto, may be executed in counterparts each of which shall be deemed as original, but all of which taken together shall constitute one and the same instrument.

Article XXIII. Antibribery and Anti-Corruption

The Government acknowledges that it has received and read Recipient's 'Prevention of Corruption - Third Party Guidelines.' Each Party agrees to perform its obligations under this Project Agreement in accordance with the applicable anti-bribery and anti-corruption laws of the territory in which such Party conducts business with the other Party as set forth herein. Each Party shall be entitled to exercise its termination right, under and in accordance with the terms of this Project Agreement, to terminate this Project Agreement immediately on written notice to the other Party, if the other Party fails to perform its material obligations in accordance with this Article XXIII.

Article XXIV. Inspection, Acceptance, & Delivery

A. Acceptance

- Upon acceptance by the AOR of any lot of vaccine under this Project Agreement and confirmation from the AO, title to such vaccine will transfer upon (a) delivery of DP to vendor-managed inventory ("VMI"), or delivery to a site designated by the Government, as initially applicable, and (b) the Government's corresponding written acceptance of each delivery. Storage as VMI may only take place up to twelve months after (b) (4), (b) (2) [redacted]

- Any deviations, out of specification ("OOS") results, or other product issues, shall be reported to the USG within 3 calendar days after initial delivery.

- When held in VMI, these materials should be maintained in Janssen's or its designated representative's quality and inventory systems. Delivered Regimens are intended for clinical use or use under Emergency Use Authorization or a BLA. Product held in VMI is subject to the following requirements:

    - Provide temperature controlled storage at the manufacturer's site approved by the Government, according to cGMP and product specifications.

    - Store Project Agreement products physically segregated from other products.

    - Ensure proper labeling of stored materials as USG property.

    - Execute stability testing of stored material in a manner consistent with the stability testing plan approved by the Government. Report interim data and results to the Government on a monthly basis.

    - Appropriately identify reserve samples that are representative of drug product shall be retained. The reserve samples consist of at least twice the quantity necessary for all tests required to determine whether the drug product meets its established specifications including a minimum of 60 months of stability testing.

    - Provide the Government access to review the security systems in place and request updates as needed.

    - Include in monthly report inventory for drug product (number of vials), including inventory quantity changes, current quantity, storage facility/location, manufacturing date, latest stability result for potency, date of next expected stability result and the current expiration date (if applicable).

    - Ensure that material being relocated for Janssen's convenience is adequately insured at no cost to the government and with AO approval.

    - Conduct testing necessary to ensure continued use of the stored material for pandemic response.

    - Make appropriate updates to the regulatory documentation supporting the continued use of the stored material for pandemic response.

    - If using a storage site, provide the quality agreement, specify the location and terms of the storage contract and receive approval by the Government.

- Notification must be made to the AO and AOR at least 10 calendar days prior to initial delivery. Exceptions are permitted if approved by the AO.

- The Government shall accept product that conforms to contract requirements based on Certificates of Analysis and certificate(s) of cGMP conformity provided by Janssen. The Government's acceptance of product will be deemed to have occurred if the Government does not provide written notice of acceptance or rejection within fourteen (14) calendar days of Janssen's provision of all applicable certificates.

- Upon receipt of the provided certificates and any inspection that was timely requested (physical or representative, i.e., pictures), the AOR will review and recommend acceptance or rejection; the AO will correspondingly notify Janssen of acceptance or rejection.

- Upon delivery of product, notification of delivery quantities and any movement must be made to the AOR and Government representatives.

- Upon request before storage in VMI or, if storage was initially ordered, after storage in VMI, unless otherwise mutually agreed upon by the Parties, DP shall be shipped, trackable by GPS, to the Government-designated sites within the continental United States.

- Janssen will retain physical risk of loss for all product stored as VMI until subsequent delivery to the Government at the Government-designated site. If product is initially delivered to a Government site instead of VMI, risk of loss will transfer upon delivery and acceptance at the Government-designated site. Notwithstanding either of the foregoing sentences, Janssen shall not be liable for loss of or damage to supplies caused by the negligence of officers, agents, or employees of the Government acting within the scope of their employment.

- Janssen will notify the AO and AOR of any storage or quality deviation for product held in VMI, within 3 calendar days.

- To the extent that Janssen is responsible for the correction, repair or replacement of Government property held in VMI and replacement upon loss or damage is feasible, the Government will accept replacement of such property.

- Vendor-managed storage of product manufactured under this Project Agreement is supported for up to twelve months after (b) (4), (b) (2) and, as such, the Government must either (a) take possession on or before the end of this period and provide Janssen with disposition instructions in sufficient time to transfer physical material from Janssen by this date or (b) bilaterally modify

this Project Agreement to extend the period of vendor management of storage prior to this date.

- The Government understands that prices identified in this contract include insurance costs applicable to material that will become Government property, including product stored as VMI.

- Janssen cannot reclaim title to product upon acceptance by the Government. Prior to expiration or termination of this Project Agreement, the Government may affect final distribution of any vaccines remaining in storage by any one or combination of the following methods:

    - The Government may elect to require shipment of the vaccine to US Government facilities.

    - The Government may direct Janssen to destroy all quantities remaining in storage. In this case, a letter of disposition will be provided to the USG.

B. Inspection

USG right to inspect product: The AO and/or the AOR may perform inspection of materials and services. Inspections of material created under this Project Agreement may be made by a duly authorized Government representative, and with reasonable notice (i.e., not less than 24 hours).

Article XXV. Foreign Access to Technology

(a) Except as authorized by the Office of Foreign Assets Control ("OFAC") in the Department of the Treasury, the Contractor shall not acquire, for use in the performance of this contract, any supplies or services if any proclamation, Executive order, or statute administered by OFAC, or if OFAC's implementing regulations at 31 CFR chapter V, would prohibit such a transaction by a person subject to the jurisdiction of the United States.

(b) Except as authorized by OFAC, most transactions involving Cuba, Iran, and Sudan are prohibited, as are most imports from Burma or North Korea, into the United States or its outlying areas. Lists of entities and individuals subject to economic sanctions are included in OFAC's List of Specially Designated Nationals and Blocked Persons at http://www.treas.gov/offices/enforcement/ofac/sdn/. More information about these restrictions, as well as updates, is available in the OFAC's regulations at 31 CFR chapter V and/or on OFAC's website at http://www.treas.gov/offices/enforcement/ofac.

(c) The Contractor shall insert this clause, including this paragraph (c), in all subcontracts.

Article XXVI.Government Observer in Recipient Facility

With seven (7) days advance notice to the Recipient in writing from the AO, the Government may place an observer in a Recipient facility that is being used for work hereunder, who shall be subject to Recipient's policies and procedures regarding security and facility access at all times while in the Recipient's facility and who shall limit its activities to observing work related to this Project Agreement. As determined by federal law and as required under this Project Agreement/Statement of Work, no Government representative shall publish, divulge, disclose or make known in any manner, or to any extent not authorized by law, any information disclosed to that person in the course of employment or official duties performed while stationed in a Recipient facility.

Article XXVII. Reporting Matters Involving Fraud, Waste and Abuse

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in ASPR funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll-free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dThe Government .gov and the mailing address is:

Office of Inspector General
Department of
Health and Human
Services TIPS
HOTLINE
P.O. Box 23489
Washington, D.C. 20026

Article XXVIII. Prohibition on Contractor Involvement with Terrorist Activities

The Recipient acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O.13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Recipient to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this Project Agreement.

Article XXIX.Survival

Articles IV (PREP Act); V (Payment); VI, Sections (B) & (C) (Disputes and Limitations on Damages); VII (Confidential Information), IX (Patent Rights), X (Data Rights) and this Article XXIX shall survive the termination provisions in Article II, Section 2.

Section XXIX.1 Close-out Procedure

If the Government funds an individual Project Agreement and then subsequently terminates the agreement or the requirements of the Project Agreement are met, the following closeout procedures apply:

(a) Definitions.

(i) "Closeout" – the process by which the Government and CMF determine that all applicable administrative actions and all required work have been completed by Janssen.

(ii) "Date of Completion" – the date on which all work is completed or the date on an amendment thereto on which the period of performance ends.

(b) Upon request, the Government shall make prompt payments to Janssen through the CMF for outstanding payments and reimbursements under the Project Agreement being closed out.

(c) Janssen shall immediately refund any balance of unobligated (unencumbered) cash that the CMF has paid and that is not authorized to be retained by Janssen for use in the performance of the Project Agreement.

(d) The CMF shall obtain from Janssen within 180 calendar days after the date of completion of an Project Agreement all financial, performance, and other reports required as a condition of the Project Agreement. The CMF may grant extensions when requested by Janssen.

(e) Reserved.

(f) Quick close-out procedures similar to FAR 42.708 shall be followed.

(g) Janssen shall account for any property received from the Government.

ATTACHMENT 1:

Janssen's Background Patents, Patent Applications and Inventions

Listed Janssen Background Intellectual Property *and Technical Data*

Attachment 1 comprises a table with the full list of pending and granted patents in the patent families listed below that, to the best of Janssen's knowledge, is accurate as of July 9, 2020. Janssen makes no representations or warranties with regards to the accuracy or completeness of that information. The Parties mutually agree that Janssen is not obligated to maintain the currency or accuracy of the information provided in the table.

Certain patent applications / patents on this list are registered at the patent office with Crucell Holland B.V. as the applicant. Crucell Holland B.V. was acquired by Johnson & Johnson in 2011 and subsequently changed its name to Janssen Vaccines & Prevention in 2016.

Certain patents on this list are owned by (b) (4) Janssen holds a license to these patents.

COVID Vaccination and Dosage Regimen:
Janssen has filed patent application(s), or is the assignee or licensee of pending patent applications including those listed below which contain(s) claims that are related to COVID Vaccines and Dosage regimens

- All patent applications and/or resulting patents (including any foreign counterparts, divisionals, continuations, or the like thereof, and any extensions thereof) that include a priority claim to (b) (4)

PER.C6® Technology and/or AdVac® Technology:

Janssen has filed patent application(s), or is the assignee or licensee of pending patent applications and/or issued patent(s), including those listed below which contain(s) claims that are related to PER.C6® technology and/or AdVac® technology.

(b) (4)

(b) (4)

[redacted]

(b) (4) [redacted]

Table X: Janssen Assertion of Data Rights Technical Data

Technical Data to be Furnished With Restrictions	***Basis for Assertion***	***Asserted Rights Category***	***Name of Person Asserting Restrictions***
(b) (4) [redacted]	[redacted]	*A*	*Janssen*
(b) (4) [redacted]	[redacted]	*A*	*Janssen*
(b) (4) [redacted]	[redacted]	*A*	*Janssen*
(b) (4) [redacted]	[redacted]	*A*	*Janssen*
(b) (4) [redacted]	[redacted]	*A*	*Janssen*
(b) (4) [redacted]	[redacted]	*A*	*Janssen*
(b) (4) [redacted]	[redacted]	*A*	*Janssen*
(b) (4) [redacted]	[redacted]	*A*	*Janssen*
(b) (4) [redacted]	[redacted]	*A*	*Janssen*
(b) (4) [redacted]	[redacted]	*A*	*Janssen*

Technical Data to be Furnished With Restrictions	*Basis for Assertion*	*Asserted Rights Category*	*Name of Person Asserting Restrictions*
(b) (4) [redacted]	[redacted]	*A*	*Janssen*
(b) (4) [redacted]	[redacted]	*A*	*Janssen*
(b) (4) [redacted]	[redacted]	*A*	*Janssen*

Table: List of pending and granted background patents as of July 9, 2020.

Internal reference	Title	Country / Region	Application Number	Application Date
(b) (4) [redacted]	[redacted]	[redacted]	[redacted]	[redacted]
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ATTACHMENT 2:

Additional OPSEC Requirements

ATTACHMENT 3:

Material Threats

Biological Threats

1 Bacillus anthracis (anthrax) and Multi-drug resistant B. anthracis (MDR anthrax)
2 Burkholderia mallei (glanders) and Burkholderia pseudomallei (melioidosis)
3 Clostridium botulinum toxin (botulism)
4 Ebola virus (Ebola hemorrhagic fever)
5 Francisella tularensis (tularemia)
6 Marburg virus (Marburg hemorrhagic fever)
7 Pandemic influenza
8 Rickettsia prowazekii (typhus)
9 Variola virus (smallpox)
10 Yersinia pestis (plague)

Chemical Threats

A. Acetylcholinesterase inhibitor nerve agents
B. Chlorine
C. Cyanide salts (potassium and sodium cyanide)
D. Hydrogen cyanide
E. Phosgene
F. Vesicants

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0058

The CLIN extended description has changed from:

PLACE HOLDER - RPP 20-11 Objective 20-11 is being authorized under CLIN 0058 for "Janssen's COVID-19 Vaccine – Large Scale Domestic Production." The total approved cost by the Government for this effort is not to exceed $1,010,000,000.00. The total amount authorized to Janssen is $1,001,650,000.00. The total amount authorized to ATI is $8,350,000.00 (broken out as $8,350,000.00 Cost and $0.00 Fixed Fee).

To:

RPP 20-11 Objective 20-11 is being awarded under CLIN 0058 for "Janssen's COVID-19 Vaccine – Large Scale Domestic Production." The total approved cost by the Government for this effort is not to exceed $1,010,000,000.00. The total amount awarded to Janssen is

$1,001,650,000.00. The total amount authorized to ATI is $8,350,000.00 (broken out as $8,350,000.00 Cost and $0.00 Fixed Fee).

.

SUBCLIN 005802 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
005802					$0.00
	Funding for CLIN 0058 CPFF Funding is being added to CLIN 0058 in the amount of $999,999,999.99. The total amount awarded to Janssen is $999,999,999.99. The total amount awarded to ATI is $0.00 (broken out as $0.00 Cost and $0.00 Fixed Fee). PURCHASE REQUEST NUMBER: 0011532810				
				ESTIMATED COST	$0.00
				FIXED FEE	$0.00
				TOTAL EST COST + FEE	$0.00
	ACRN GT CIN: GFEBS001153281000001				$999,999,999.99

SUBCLIN 005803 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
005803					$0.00
	Funding for CLIN 0058 CPFF Funding is being added to CLIN 0058 in the amount of $1,650,000.01. The total amount awarded to Janssen is $1,650,000.01. The total amount awarded to ATI is $0.00 (broken out as $0.00 Cost and $0.00 Fixed Fee). PURCHASE REQUEST NUMBER: 0011532810				
				ESTIMATED COST	$0.00
				FIXED FEE	$0.00
				TOTAL EST COST + FEE	$0.00
	ACRN GU CIN: GFEBS001153281000002				$1,650,000.01

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 005802:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The following Acceptance/Inspection Schedule was added for SUBCLIN 005803:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by $1,001,650,000.00 from $6,328,970,669.79 to $7,330,620,669.79.

SUBCLIN 005802:
Funding on SUBCLIN 005802 is initiated as follows:

ACRN: GT

CIN: GFEBS001153281000001

Acctng Data: 021202020212040000664643255 S.0074658.5.14 6100.9000021001

Increase: $999,999,999.99

Total: $999,999,999.99

Cost Code: A5XAH

SUBCLIN 005803:
Funding on SUBCLIN 005803 is initiated as follows:

ACRN: GU

CIN: GFEBS001153281000002

Acctng Data: 021202020212040000664643255 S.0074658.5.14.1 6100.9000021001

Increase: $1,650,000.01

Total: $1,650,000.01

Cost Code: A5XAH

(End of Summary of Changes)