

| | | | | | | | | | |
|--|--|--|-----------------------------------|-------------------------------------|--|--|--|----------------------------------|------------|
| SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS <i>OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, AND 30</i> | | | | 1. REQUISITION NUMBER 0011648600 | | PAGE 1 OF 48 | | | |
| 2. CONTRACT NO. W911QY21C0031 | | 3. AWARD/EFFECTIVE DATE 07-Jun-2021 | | 4. ORDER NUMBER | | 5. SOLICITATION NUMBER | | 6. SOLICITATION ISSUE DATE | |
| 7. FOR SOLICITATION INFORMATION CALL: | | | a. NAME | | | b. TELEPHONE NUMBER (No Collect Calls) | | 8. OFFER DUE DATE/LOCAL TIME | |
| 9. ISSUED BY W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011 TEL: FAX: 508-233-5700 | | | CODE W911QY | | 10. THIS ACQUISITION IS <input checked="" type="checkbox"/> UNRESTRICTED OR <input type="checkbox"/> SET ASIDE: _____ % FOR: <input type="checkbox"/> SMALL BUSINESS <input type="checkbox"/> WOMEN-OWNED SMALL BUSINESS (WOSB) <input type="checkbox"/> HUBZONE SMALL BUSINESS <input type="checkbox"/> ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM <input type="checkbox"/> SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS <input type="checkbox"/> EDWOSB <input type="checkbox"/> 8(A) NAICS: 325412 SIZE STANDARD: 1,250 | | | | |
| 11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED <input checked="" type="checkbox"/> SEE SCHEDULE | | | 12. DISCOUNT TERMS Net 30 Days | | 13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700) <input type="checkbox"/> | | 13b. RATING | | |
| 15. DELIVER TO SEE SCHEDULE | | | CODE | | 16. ADMINISTERED BY SEE ITEM 9 | | | | |
| 17a. CONTRACTOR/OFFEROR MERCK SHARP & DOHME CORP. MERCK (b) (6) 2000 GALLOPING HILL RD KENILWORTH NJ 07033-1310 TELEPHONE NO. | | | CODE 6B2S4 | | FACILITY CODE | | 18a. PAYMENT WILL BE MADE BY DEFENSE FINANCE AND ACCOUNTING SERVICE DFAS-INDY VP GFEB5 8899 E 56TH STREET INDIANAPOLIS IN 46249-3800 | | |
| 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER <input type="checkbox"/> | | | | | 18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a. UNLESS BLOCK BELOW IS CHECKED <input checked="" type="checkbox"/> SEE ADDENDUM | | | | |
| 19. ITEM NO. | | 20. SCHEDULE OF SUPPLIES/ SERVICES | | | 21. QUANTITY | | 22. UNIT | 23. UNIT PRICE | 24. AMOUNT |
| | | SEE SCHEDULE | | | | | | | |
| 25. ACCOUNTING AND APPROPRIATION DATA See Schedule | | | | | | | 26. TOTAL AWARD AMOUNT (For Govt. Use Only) \$1,207,999,848.00 | | |
| <input type="checkbox"/> 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1. 52.212-4. FAR 52.212-3. 52.212-5 ARE ATTACHED. ADDENDA <input type="checkbox"/> ARE <input type="checkbox"/> ARE NOT ATTACHED | | | | | <input type="checkbox"/> 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA <input type="checkbox"/> ARE <input type="checkbox"/> ARE NOT ATTACHED | | | | |
| <input checked="" type="checkbox"/> 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED. | | | | | <input type="checkbox"/> 29. AWARD OF CONTRACT: REF. OFFER DATED . YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS: | | | | |
| 30a. <input checked="" type="checkbox"/> (b) (6) | | | | | 31a. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER) (b) (6) | | | | |
| 30b. NAME AND TITLE OF SIGNER (TYPE OR PRINT) (b) (6) | | | 30c. DATE SIGNED 6/7/2021 | | 31b. NAME OF CONTRACTING OFFICER (TYPE OR PRINT) (b) (6) | | | 31c. DATE SIGNED 6/7/2021 | |

**SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS
(CONTINUED)**

| 19. ITEM NO. | 20. SCHEDULE OF SUPPLIES/ SERVICES | 21. QUANTITY | 22. UNIT | 23. UNIT PRICE | 24. AMOUNT |
|----------------------------|---------------------------------------|-----------------|-------------|-------------------|---------------|
| <p>SEE SCHEDULE</p> | | | | | |

32a. QUANTITY IN COLUMN 21 HAS BEEN
 RECEIVED INSPECTED ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED: _____

| | | |
|--|-----------|---|
| 32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE | 32c. DATE | 32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE |
|--|-----------|---|

| | |
|--|---|
| 32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE | 32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE |
| | 32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE |

| | | | | |
|--|--------------------|---------------------------------|--|------------------|
| 33. SHIP NUMBER <input type="checkbox"/> PARTIAL <input type="checkbox"/> FINAL | 34. VOUCHER NUMBER | 35. AMOUNT VERIFIED CORRECT FOR | 36. PAYMENT <input type="checkbox"/> COMPLETE <input type="checkbox"/> PARTIAL <input type="checkbox"/> FINAL | 37. CHECK NUMBER |
|--|--------------------|---------------------------------|--|------------------|

| | | |
|------------------------|------------------------|-------------|
| 38. S/R ACCOUNT NUMBER | 39. S/R VOUCHER NUMBER | 40. PAID BY |
|------------------------|------------------------|-------------|

| | | | |
|---|-----------------------------------|--------------------------------------|-----------------------|
| 41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT | 42a. RECEIVED BY (<i>Print</i>) | | |
| 41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER | 41c. DATE | 42b. RECEIVED AT (<i>Location</i>) | |
| | | 42c. DATE REC'D (<i>YY/MM/DD</i>) | 42d. TOTAL CONTAINERS |

Section SF 1449 - CONTINUATION SHEET

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|-------------------|-----------|------|------------|--------------------|
| 0001 | | 1,696,629 | Each | \$712.00 | \$1,207,999,848.00 |

Oral Antiviral MK-4482 (molnupiravir)
FFP

The contractor shall produce, store and distribute 1,696,629 treatment courses of the oral antiviral, MK-4482 IAW the Statement of Work (SOW) and CDRLs (Exhibit A) on this contract.

A unit is defined as one full treatment course.

FOB: Origin (Shipping Point)
PROJECT: COVID-19 CAG
PSC CD: 6505

| | |
|---------|--------------------|
| NET AMT | \$1,207,999,848.00 |
|---------|--------------------|

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|-------------------|----------|------|------------|--------|
| 000101 | | | | | \$0.00 |

ACRN AA @ \$618,999,984.00
FFP
PURCHASE REQUEST NUMBER: 0011648600

| | |
|---------|--------|
| NET AMT | \$0.00 |
|---------|--------|

| | |
|--------------------------|------------------|
| ACRN AA | \$618,999,984.00 |
| CIN: GFEB001164860000001 | |

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|-------------------|----------|------|------------|--------|
| 000102 | | | | | \$0.00 |

ACRN AB @ \$588,999,864.00
 FFP
 PURCHASE REQUEST NUMBER: 0011648600

| | |
|---------|--------|
| NET AMT | \$0.00 |
|---------|--------|

| | |
|---------------------------|------------------|
| ACRN AB | \$588,999,864.00 |
| CIN: GFEBS001164860000002 | |

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|-------------------|----------|------|------------|--------|
| 0002 | | 1 | Job | | NSP |

Technical Data
 FFP
 The contractor shall deliver Technical Data IAW Contract Data Requirements List (CDRL) IAW deliverables, Exhibit A.
 FOB: Destination
 MFR PART NR: N/A
 PROJECT: COVID-19 CAG
 PSC CD: 6505

NET AMT

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|-------------------|----------|------|------------|---------|
| 1001 | | (b) (4) | Each | \$712.00 | (b) (4) |

OPTION

Oral Antiviral MK-4482 (molnupiravir)
FFP

The contractor shall produce, store, and distribute (b) (4) treatment courses of the oral antiviral, MK-4482 IAW the Statement of Work (SOW) and CDRLs (Exhibit A) on this contract.

A unit is defined as one full treatment course.

If exercised, the option shall be awarded no later than (b) (4)

The government shall provide 15 days notification to exercise the option.

FOB: Origin (Shipping Point)
PROJECT: COVID-19 CAG
PSC CD: 6505

NET AMT

\$(b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|-------------------|----------|------|------------|---------|
| 2001 | | (b) (4) | Each | \$712.00 | (b) (4) |

OPTION

Oral Antiviral MK-4482 (molnupiravir)
FFP

The contractor shall produce, store, and distribute (b) (4) treatment courses of the oral antiviral, MK-4482 IAW the Statement of Work (SOW) and CDRLs (Exhibit A) on this contract.

A unit is defined as one full treatment course.

If exercised, the option shall be awarded no later than (b) (4).

The government shall provide 15 days notification to exercise the option.

FOB: Origin (Shipping Point)
PROJECT: COVID-19 CAG
PSC CD: 6505

NET AMT

(b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|-------------------|----------|------|------------|---------|
| 3001 | | (b) (4) | Each | \$712.00 | (b) (4) |

OPTION

Oral Antiviral MK-4482 (molnupiravir)
FFP

The contractor shall produce, store, and distribute (b) (4) treatment courses of the oral antiviral, MK-4482 IAW the Statement of Work (SOW) and CDRLs (Exhibit A) on this contract.

A unit is defined as one full treatment course.

If exercised, the option shall be awarded no later than (b) (4).

The government shall provide 15 days notification to exercise the option.

FOB: Origin (Shipping Point)
PROJECT: COVID-19 CAG
PSC CD: 6505

NET AMT

(b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|----------------|--|----------|------|------------|---------|
| 4001 OPTION | Oral Antiviral MK-4482 (molnupiravir) FFP | (b) (4) | Each | \$712.00 | (b) (4) |

The contractor shall produce, store, and distribute (b) (4) treatment courses of the oral antiviral, MK-4482 IAW the Statement of Work (SOW) and CDRLs (Exhibit A) on this contract.

A unit is defined as one full treatment course.

If exercised, the option shall be awarded no later than (b) (4)

The government shall provide 15 days notification to exercise the option.

FOB: Origin (Shipping Point)
PROJECT: COVID-19 CAG
PSC CD: 6505

NET AMT

(b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---------|-------------------|----------|------|------------|---------|
| 5001 | | (b) (4) | Each | \$712.00 | (b) (4) |

OPTION

Oral Antiviral MK-4482 (molnupiravir)
FFP

The contractor shall produce, store, and distribute (b) (4) treatment courses of the oral antiviral, MK-4482 IAW the Statement of Work (SOW) and CDRLs (Exhibit A) on this contract.

A unit is defined as one full treatment course.

If exercised, the option shall be awarded no later than (b) (4).

The government shall provide 15 days notification to exercise the option.

FOB: Origin (Shipping Point)
PROJECT: COVID-19 CAG
PSC CD: 6505

NET AMT

(b) (4)

STATEMENT OF WORK

ADDENDUM: The following pages hereby supplements FAR 52.212-4

Statement of Work

C.1 EXECUTIVE SUMMARY (Scope of Project):

Manufacturing shall occur using cGMP manufacturing processes for drug product manufacturing, pack and label. The specific objective is the acquisition of 1,696,629 treatment courses (b) (4) for a targeted US population for delivery twelve weeks post Emergency Use Authorization (EUA) with the option to acquire additional treatment courses in (b) (4) unit increments up to an additional (b) (4). The contractor shall also provide storage and distribution.

The product to be produced and delivered includes the antiviral therapeutic, molnupiravir. Purchase is contingent upon U.S. Food and Drug Administration (FDA) issuance of an EUA or approval of an NDA for use of the drug to treat COVID-19 consistent with the following Target Product Profile:

| | |
|----------------|--|
| Indication | Treatment of COVID-19 in non-hospitalized adult patients with mild or moderate disease |
| Dosing Regimen | Q12H for 5 days |
| Route | Oral |
| Efficacy | Statistically significant superiority of molnupiravir compared to placebo assessed by the percentage of participants who are hospitalized and/or die through Day 29. Ongoing phase 3 trial in outpatients at high risk for severe COVID-19 meets its primary endpoint and data as assessed by FDA is sufficient for an EUA |
| Safety | Acceptable safety profile and positive benefit/risk balance |
| Stability | Stability data to support (b) (4) |

C.2 TASKS

Clinical trials, FDA engagement, manufacturing scale-up, and supply-chain activities are outside the scope of the agreement.

Task 1: The contractor shall establish a quality agreement with the US Government on requirements for the US Government to accept packaged drug product as a completed deliverable. Quality agreement must be negotiated within the first 30 days of award and prior to Government acceptance of drug product.

Task 2: The contractor shall provide a Product Development Source Material and Manufacturing Plan within 30 days of award to fulfill the US Government order. The manufacturing plan should include all materials required for drug substance/active pharmaceutical ingredient manufacturing and finished drug product, an acquisition plan for acquiring necessary materials, all key subcontractors and manufacturing sites, and a detailed schedule for providing the final product to the US Government.

Task 3: The contractor shall manufacture the therapeutic product(s) using an established manufacturing process for bulk drug substance and fill and finished drug product, with a ramp-up capacity plan that provides enough doses to meet the desired number of treatment courses.

Task 4: Storage. The contractor shall store the packaged drug product under cGMP conditions until the U.S. Government has directed the allocation of the product. The contractor will store the packaged drug product for a period of up to (b) (4) after product acceptance by the U.S. Government.

Task 5: Distribution. The contractor shall distribute the product as directed by the U.S. Government (USG) through the contractor's commercial distribution network (b) (4)

Transfer of product to USG and distribution will not occur unless, on the date of transfer, there is an active EUA or FDA approval/licensure for the product authorizing use of the drug to treat COVID-19.

Task 6: The contractor will provide product to the USG for live virus variant and animal model testing subject to a Material Transfer Agreement (MTA) to be executed by the Parties.

Task 7: To the extent consistent with the terms of any EUA as well as applicable legal, regulatory or compliance requirements or guidance, including but not limited to requirements or guidance under the Food Drug and Cosmetic Act the contractor will develop learning material to assist in administration and increase uptake of their drug to the public including but not limited to pamphlets, infomercials, websites, etc. (b) (4)

(b) (4)

(b) (4)



Task 8: Program Management Activities: The contractor shall establish the capacity in compliance with Food and Drug Administration (FDA) current good manufacturing practices (cGMP) regulations, and Biosafety Level standards if applicable. The contractor shall be responsible for management of all activities, including but not limited to, subcontractors to meet the goals of the contract, including holding routine meetings with USG, and completion of meeting minutes. On a monthly basis, the contractor shall provide a monthly report (A007) that includes capacity availability and utilization, as well as any issues that affect the operational availability of the reserved capacity.

The contractor shall provide minutes and reports in accordance with the following deliverables and the Contract Data Requirements List (CDRL), Section J, Exhibit A.

Post Award Teleconference. The contractor shall complete an initial teleconference after contract award in accordance with CDRL A001. The goal of this teleconference is to outline activities for the next 30 days and discuss agenda items for the post-award Kickoff Meeting (CDRL A002).

Kickoff Meeting. The Contractor shall complete a Kickoff meeting after contract award in accordance with CDRL A002. This will occur within a month of contract award, pending concurrence by the contracting officer.

Every 2 weeks Teleconference. The Contractor shall participate in teleconferences every 2 weeks, with BARDA to discuss the performance on the contract in accordance with CDRL A003. Meeting frequency can be increased or decreased with agreement between both parties as needed during the course of the Project.

Quarterly Meetings. At the discretion of the government the Contractor shall hold recurring teleconferences in accordance with CDRL A004.

FDA Meeting Minutes. Contractor shall notify BARDA 24 hours of the receiving notification from the FDA that a meeting date for the Type A, B or C meeting has been granted OR within 24 hours of meeting occurrence for ad hoc meetings in accordance with CDRL A005. The Contractor shall forward FDA-issued preliminary comments and final minutes of any meeting with the FDA to BARDA.

Daily check in with project staff for COVID-19 Contract. Contractor shall participate in a daily check-in update if necessary with the Project Managers and additional project staff as needed (via teleconference or email) in accordance with CDRL A006. Potential triggers for the check-in include but are not limited to regulatory status changes, manufacturing and or/distribution problems that will affect delivery,

Monthly Progress Reports. A consolidated submission of all slides and data presented at the biweekly telecons will serve as the monthly report in accordance with CDRL A007. The report only consists of a summary of quantity of product delivered, when and location of the delivery.

Draft and Final Technical Progress Report. A draft Final Technical Progress Report containing a summation of the work performed over the entire Contract. This report shall be in sufficient detail to fully describe the progress achieved under all milestones. Report should contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained during the Contract. Descriptions and rationale for activities and milestones that were not completed as planned should be provided. The draft report shall be duly marked as 'Draft' in accordance with CDRL A008. The final report should be submitted in accordance with CDRL A009. This report should be a comprehensive summary of the quantity of product delivered, when it was delivered and where.

Product Development Source Material and Manufacturing Reports. The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites in accordance with CDRL A010. The contract will provide manufacturing reports and manufacturing dose tracking projections/actuals utilizing the "COVID-19 Dose Tracking Templates" or similar. This deliverable only applies to material manufactured for this project, and for which the government has agreed to purchase.

Contractor Locations. The contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, an overall manufacturing point of contact, and work performed per location, to include sub-contractors in accordance with CDRL A011.

Pandemic Management Plan. A pandemic facility and/or operational management plan including change procedures from normal to pandemic operations. Contractor will prepare an operational plan to continue operations in the event of a declared pandemic emergency in accordance with CDRL A012.

Supply Chain and Distribution Tracking. Distribution Concept of Operations. BARDA, and MCM Manufacturers play an important role in the distribution of therapeutics to the American people under a nationwide response. BARDA will work with the manufacturer to monitor what is in the manufacturing pipeline using a dose tracking templates. Contractor will relay final drug product information as it is being released to the BARDA/ASPR for allocation and ordering by state public health departments. This information will be returned to BARDA, the contractor and distributor. Distributors will use that information to ship therapeutics in bulk to sites of administration/end user. This will be done in accordance with CDRL A013.

Distribution Plan. This plan shall describe the Contractor's process to distribute EUA-or BLA-approved product to point of care facilities, necessary to meet the Government's need for administration. The plan shall comply with applicable provisions of the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov 27, 2013), taking into account FDA's regular guidance for the COVID-19 public health response. This will be done in accordance with CDRL A014.

Distribution Memorandum of Understanding. This document is an understanding between ASPR, Merck, and the distributors to set forth the terms for each party to work together in accordance with CDRL A015.

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

[description, choice, rationale]; microbiological attributes documents and plans; compatibility documents (e.g., precipitation); assay development and validation, stability plan; and any associated risks. This will be done in accordance with CDRL A016.

Quality Management Plan. Plan may include, but is not limited to the manufacturing 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. This will done in accordance with CDRL A017.

Quality Agreement. Agreement will determine the conditions of acceptance by the USG of the purchased product. No product will be accepted by the USG until a quality agreement is in place in accordance with CDRL A018.

Release documentation for doses to be delivered. In accordance with CDRL A019 contractor will deliver Certificate of Analysis and Certificate of Compliance at least 14 days prior to delivery.

Security Plan. In accordance with CDRL A020 the contractor will deliver a security plan within 60 days of award.

Supply Chain Resiliency Plan. In accordance with CDRL A021 the contractor will deliver a supply chain resiliency plan within 60 days of award.

Manufacturing Data Requirements. In accordance with CDRL A022 the contractor will deliver manufacturing data requirements within 30 days of award.

BARDA Audit. Contractor shall accommodate for cause visits by BARDA. If BARDA, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to BARDA in accordance with CDRL A023.

FDA Inspections. In the event of an FDA inspection that occurs in relation to this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the COR and KO with copies of the plan for addressing areas of nonconformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product in accordance with CDRL A024.

QA Audits. BARDA reserves the right to participate in QA audits performed by the Contractor. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of nonconformance to FDA regulations for GMP, guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action in accordance with CDRL A025.

Integrated Master Schedule. The contractor shall provide an IMS that illustrates project tasks, dependencies, durations throughout the period of performance, and milestones (GO/NO-GO) in accordance with CDRL A026. The IMS must map to the WBS, and provide baseline, and actual or forecast dates for completion of tasks. The IMS may be limited to those tasks associated with delivery of the product and other deliverables identified in the Statement of Work.

Deviation Notification and Mitigation Strategy. Contractor shall provide a process for changing IMS activities associated with cost and schedule as baselined in accordance with CDRL A027. Contractor shall

notify BARDA of significant proposed changes the IMS defined as or schedule slippage of more than 30 days, which would require a PoP extension. Contractor shall provide a high level management strategy for risk mitigation

Incident Report. Contractor shall communicate to BARDA and document all critical programmatic concerns, issues, or probable risks that have or are likely to significantly impact project schedule in accordance with CDRL A028. "Significant" is frequently defined as a 10% or greater schedule variance within a control account, but should be confirmed in consultation with the COR. Incidents that present liability to the project even without schedule impact, must also be reported.

FDA Correspondence and Submissions. The Contractor shall provide BARDA with all material regulatory documentation submitted to the FDA and related responses received from the FDA. This will be done in accordance with CDRL A029.

Provision of Public Law 115-92 Sponsor Authorization Letter. The Contractor shall submit Public Law 115-92 Sponsor Authorization Letter in the Contractor's format that will be delivered to the designated OWS POC(s). This will be done in accordance with CDRL A030.

Press Releases. Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases in accordance with CDRL A031.

Educational Materials. Contractor will develop learning material to assist in administration and increase appropriate uptake of their drug to the public including but not limited to pamphlets, infomercials, websites, etc., subject to FDA guidance, regulation, and/or review in accordance with CDRL A032.

C.3 SECURITY

The contractor shall comply with all Operation Warp Speed Security requirements in Section J Attachment 0001, Security Requirements.

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

| CLIN | INSPECT AT | INSPECT BY | ACCEPT AT | ACCEPT BY |
|--------|-------------|------------|-------------|------------|
| 0001 | Origin | Government | Origin | Government |
| 000101 | N/A | N/A | N/A | N/A |
| 000102 | N/A | N/A | N/A | N/A |
| 0002 | Destination | Government | Destination | Government |
| 1001 | Origin | Government | Origin | Government |
| 2001 | Origin | Government | Origin | Government |
| 3001 | Origin | Government | Origin | Government |
| 4001 | Origin | Government | Origin | Government |
| 5001 | Origin | Government | Origin | Government |

TERMS FOR INSPECTION/ACCEPTANC

E1. Inspection and Acceptance

Inspection shall be at origin at the contractor's plant, conducted by the USG technical representative in accordance with the Quality Assurance (QA) plan. Acceptance shall be at origin by the ACC-APG Contracting Officer. All documentation required for both Inspection and Acceptance shall be uploaded into Wide Area Workflow (WAWF) by the contractor.

DELIVERY SPECIFICATIONS

F.1 Delivery Schedule

Base period: The contractor shall release and make available for distribution a minimum of (b) (4) treatment courses (b) (4) from the date of regulatory authorization. An additional (b) (4) courses shall be released and made available for distribution (b) (4) after regulatory authorization. The remaining (b) (4) courses shall be released and made available for distribution (b) (4) after regulatory authorization.

Option periods: The contractor shall release and make available for distribution a minimum of (b) (4) courses (b) (4) after the option exercise date. The remaining (b) (4) shall be released and made available for distribution (b) (4) after option exercise. In the event two options are exercised within 15 days of one another, supply shall be released and made available for distribution in (b) (4) courses per (b) (4) tranches, beginning (b) (4) after the first option exercise date.

DELIVERY INFORMATION

| CLIN | DELIVERY DATE | QUANTITY | SHIP TO ADDRESS | DODAAC / CAGE |
|--------|-----------------------------------|----------|--|---------------|
| 0001 | POP 07-JUN-2021 TO 15-JUN-2022 | N/A | N/A FOB: Origin (Shipping Point) | |
| 000101 | N/A | N/A | N/A | N/A |
| 000102 | N/A | N/A | N/A | N/A |
| 0002 | POP 07-JUN-2021 TO 15-JAN-2023 | N/A | BARDA (b) (6) BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT AUTH 200 C STREET, SW WASHINGTON DC 20024 (b) (6) FOB: Destination | W56XNH |
| 1001 | POP 31-JAN-2022 TO 15-SEP-2022 | N/A | N/A FOB: Origin (Shipping Point) | |

| | | | |
|------|-----------------------------------|-----|-------------------------------------|
| 2001 | POP 28-FEB-2022 TO 15-OCT-2022 | N/A | N/A FOB: Origin (Shipping Point) |
| 3001 | POP 31-MAR-2022 TO 15-NOV-2022 | N/A | N/A FOB: Origin (Shipping Point) |
| 4001 | POP 30-APR-2022 TO 15-DEC-2022 | N/A | N/A FOB: Origin (Shipping Point) |
| 5001 | POP 31-MAY-2022 TO 15-JAN-2023 | N/A | N/A FOB: Origin (Shipping Point) |

CONTRACT ADMINISTRATION

GOVERNMENT CONTRACT ADMINISTRATION

In no event shall any understanding or agreement, contract modification, change order, or other matter in deviation from the terms of this contract between the Contractor and a person other than the Contracting Officer be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the Contracting Officer.

G.1 Procuring Contracting Officer:

(b) (6)
ACC Joint COVID-19 Response Division

Contract Specialist:

(b) (6)
ACC Joint COVID-19 Response Division

G.2 GOVERNMENT TECHNICAL POINT OF CONTACT

(b) (6)
200 C Street, SW
Washington, DC 20024

G.3 CONTRACTOR'S CONTRACT ADMINISTRATION

(b) (6)
Merck & Co., Inc
351 N. Sumneytown Pike
North Wales, PA 19454

G.4 PLACES OF PERFORMANCE

Merck Sharp & Dohme Corporation
2000 Galloping Hill Rd
Kenilworth, New Jersey, 07033-1310.

G.5 NOTIFICATION OF REVISIONS AND CHANGE

Notification of revision or changes to names or email addresses will be provided by official correspondence from the PCO or office of the PCO in lieu of a contract modification. This does not apply to any such revisions or changes in the event this contract includes a key personnel clause.

ACCOUNTING AND APPROPRIATION DATA

AA: 0212021202220400000665654255 S.0074658.5.38.1 6100.9000021001
 COST CODE: A5XAH
 AMOUNT: \$618,999,984.00

AB: 0212021202220400000665654255 S.0074658.5.38 6100.9000021001
 COST CODE: A5XAH
 AMOUNT: \$588,999,864.00

| ACRN | CLIN/SLIN | CIN | AMOUNT |
|------|-----------|---------------------|---------|
| AA | 000101 | GFEB001164860000001 | (b) (4) |
| AB | 000102 | GFEB001164860000002 | (b) (4) |

CLAUSES INCORPORATED BY FULL TEXT

252.232-7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (DEC 2018)

(a) Definitions. As used in this clause—

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

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

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

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

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

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

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

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

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

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

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

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

COMBO

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

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

N/A

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

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

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

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

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

Routing Data Table*

| <i>Field Name in WAWF</i> | <i>Data to be entered in WAWF</i> |
|---------------------------|-----------------------------------|
| Pay Official DoDAAC | HQ0490 |
| Issue By DoDAAC | W911QY |
| Admin DoDAAC** | W911QY |
| Inspect By DoDAAC | W56XNH |
| Ship To Code | (b) (4) |

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

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

(g) WAWF point of contact.

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

(b) (6)

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

(End of clause)

FOR REFERENCE:DFARS PGI 204.7108 Payment Instructions Table

https://www.acq.osd.mil/dpap/dars/pgi/pgi_hm/current/PGI204_71.htm#payment_instructions

SPECIAL CONTRACT REQUIREMENTS

H.1 Disclosure of Information:

Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information relating to product delivery timing or sites that is developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the KO which the KO will provide in accordance with OWS or other Government policies and/or guidance. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency. The Contractor shall comply with all applicable Government requirements for protection of non-public Government or third-party information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress.

Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the delivery timing or sites, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations. No information related to data obtained under this contract relating to delivery timing or sites shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions. The exceptions identified in this paragraph apply to all disclosures under this Section H.3 except to the extent that a disclosure is otherwise prohibited by law.

H.2 Publication and Publicity

The contractor shall not release any press releases, or any other publications, to the extent addressing delivery of product under this contract without written notice in advance to the Government.

- (a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission addressing delivery timing or sites to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published.
- (b) Unless authorized in writing by the KO, the contractor shall not display the DoD logo including Operating Division or Staff Division logos on any publications.
- (c) The contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies DoD approval or endorsement of the product(s) or service(s) provided.
- (d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract Number W911QY-21-C-0031."

H.3 Confidentiality of Information

1. Confidential information, as used in this article, means non-public information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.
2. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.
3. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.
4. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.
5. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.
6. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.
7. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ALL REQUIREMENTS OF THIS SECTION MUST BE PASSED TO ALL SUB-CONTRACTOR.

H.4 Regulatory Rights

This contract involves supply of a product that requires FDA pre-market approval or clearance before commercial authorization. Contractor is seeking FDA authorization or clearance for the commercialization of MK-4482, Merck therapeutic for SARS-CoV-2 Coronavirus (the “Technology”). The Contractor is the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), emergency use authorization (EUA), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) for the Technology. As the Sponsor of the Regulatory Application to FDA (as the terms “sponsor” and “applicant” are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), the Contractor has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application. Accordingly, the Contractor and the Government agree to the following:

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

(b) Rights of Reference. The U.S. Government will be granted a right of reference as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule) to any Regulatory Application submitted in support of the Technology, solely for use to develop medical countermeasures (MCM) to the material threats listed on Attachment 0005. When it desires to exercise this right, the U.S. Government agrees to notify Contractor in writing describing the request along with sufficient details for Contractor to evaluate the request, and Merck will not unreasonably decline to generate and provide a mutually agreeable letter of cross-reference for the U.S. Government to file with the appropriate FDA office. The parties agree that it will not be unreasonable for Contractor to decline to provide the U.S. Government letter of cross-reference if Contractor at the time of such request is conducting a program for the research and development of a therapeutic product directed to the threat for which the U.S. Government is requesting the right of reference. The U.S. Government will also be granted a right of reference to any Regulatory Application submitted in support of the Technology, solely for use to develop the Technology, if Merck is required to provide the Government with access to the Technology under Section H.8. When it desires to exercise this right, the U.S. Government agrees to notify Merck in writing describing the request along with sufficient details for Merck to generate a letter of cross-reference for the U.S. Government to file with the appropriate FDA office. The U.S. Government agrees that in all cases such letters of cross-reference may contain reporting requirements to enable Merck to comply with its own pharmacovigilance reporting obligations to the FDA and other regulatory agencies. Nothing in this paragraph alters the U.S. Government’s data rights as articulated in other provisions of the contract.

H.5 Regulatory Compliance

1. The manufacturing described in the Statement of Work will comply with Current Good Manufacturing Practices (cGMP) regulations at 21 CFR 210 and 211. Production shall occur using cGMP manufacturing process, fully compliant with 21 CFR 210 and 211, for bulk drug substance and fill and finished drug product, with a ramp-up capacity that provides doses sufficient to meet Contractor’s obligations under this Agreement.
2. Production and distribution shall comply with applicable provisions of the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov 27, 2013), taking into account FDA’s regular guidance for the COVID-19 public health response.

H.6 Public Readiness and Emergency Preparedness (PREP) Act:

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

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

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

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

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

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

The Government may not use, or authorize the use of, any products or materials provided under this contract, unless such use occurs in the United States (or a U.S. territory where U.S. law applies such as embassies, military 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 Merck prior to use and, if the parties disagree on such use, the dispute will be resolved according to the “Disputes Clause” (52.233-1)

The items and technology covered by this Contract are being developed for both civil and military applications.

(b) (4)



H.8 Ensuring Sufficient Supply of the Product

1. In recognition of the Government’s need to provide sufficient quantities of a COVID-19 therapeutic in the amounts contemplated under this Agreement, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet its needs. This remedy is not available to the Government unless and until both of the following conditions ((a) and (b)) are met:

(a) Merck gives written notice, required to be submitted to the Government no later than 15 business days, of:

- i. any formal management decision to terminate manufacturing of this product therapeutic prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons or;
- ii. any formal management decision to discontinue sale of this product therapeutic to the Government prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons; or
- iii. any filing that anticipates Federal bankruptcy protection; and

(b) Merck has submitted an Emergency Use Authorization application under §564 of the FD&C Act or a new drug application provisions of the Food, Drug and Cosmetics Act.

2. If both conditions listed in section 1 occur, Merck, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of this product therapeutic with a third party solely for the purpose of carrying out the remaining obligations under this contract:

(a) a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Merck Background Patent, Copyright, other Merck Intellectual Property, Merck Know-How, Merck Technical Data rights necessary to manufacture doses of the MK-4482 therapeutic subject to Merck's ability to obtain the consent to sublicense under an applicable Ridgeback license, which Merck shall reasonably pursue in good faith;

(b) necessary FDA regulatory filings or authorizations owned or controlled by Merck related to this product therapeutic and any confirmatory instrument pertaining thereto; and

(c) any outstanding Deliverables contemplated or materials purchased under this contract.

3. This remedy will remain available until the end of the contract.

H.9 Transportation to Final Destination

During the course of performance under this contract, the Government may require storage of the drug product before delivery to the final location. In these circumstances, the Government will accept FDP at the contractor facility (Origin). The contractor; however, shall continue to be responsible for secure delivery of the therapeutic to its final destination as identified on this contract. (b) (4)

H.10 Intellectual Property Rights

(b) (4)

H.11 Termination

The Government may terminate this contract for convenience or cause in accordance with FAR 52.212-4(l) and (m), respectively. Additionally, in the event that the FDA does not issue an EUA or approve an NDA for the use of MK-4482 to treat COVID-19 (b) (4), and the Government subsequently terminates this contract for convenience, the parties agree that no costs incurred prior to the Government's termination under this clause will be reimbursed

H.12 (b) (4)

(b) (4)

H.13 Donation of Excess Product

A. In the event the Government determines that doses of MK-4482 funded under the contract are no longer needed by the Government, the Government may donate remaining doses to any foreign nation that has an active marketing approval in place for use of MK-4482 at the time of donation or, if no marketing approval is in place, has an active regulatory authorization and has entered into an indemnification agreement with Merck that covers donated doses.

B. The Government shall notify Contractor prior to any planned donation to a foreign nation. Contractor agrees to work with the Government in good faith to ensure all applicable regulatory submissions, import/export permits, and other requirements for donation are completed in advance of shipment to the extent that donation is authorized under Paragraph A above.

C. Merck will be responsible for shipment of MK-4482 to the receiving foreign nation; provided, however, Merck shall have no obligation to repackage or relabel the courses already purchased by the USG for delivery to the U.S. market and provided further that Merck shall only be responsible for shipment of the courses of MK-4482 to one reasonable location within the receiving foreign nation, or as otherwise agreed between the Parties.

D. The parties acknowledge that Article H.6 regarding PREP Act coverage does not apply to the provision of any doses under this paragraph to a foreign nation. The USG makes no representations as to PREP Act coverage thereto. Contractor assumes the risk of liability for use of these products in foreign jurisdictions and any immunity or indemnity arrangements in a foreign jurisdiction are the responsibility of Contractor.

H.14 Special License Agreement

(b) (4)

(b) (4)

This agreement does not alter any rights that the U.S. Government may have previously obtained under other agreements with third parties.

Section B CLIN 0001 is full compensation to the Contractor for all of the deliverables and rights granted by this contract inclusive of all contract clauses.

(b) (4)

H.15. Subject Inventions Not Expected

The Government acknowledges that it is not funding additional research or development of the drug product under this contract, or CMC/process development in respect thereof. As such, neither the Contractor nor the Government expect that conception or reduction to practice of any Subject Inventions will result from performance under this contract.

CLAUSES INCORPORATED BY REFERENCE

| | | |
|----------------|--|----------|
| 52.203-3 | Gratuities | APR 1984 |
| 52.203-12 | Limitation On Payments To Influence Certain Federal Transactions | JUN 2020 |
| 52.204-4 | Printed or Copied Double-Sided on Postconsumer Fiber Content Paper | MAY 2011 |
| 52.204-13 | System for Award Management Maintenance | OCT 2018 |
| 52.204-18 | Commercial and Government Entity Code Maintenance | AUG 2020 |
| 52.204-19 | Incorporation by Reference of Representations and Certifications. | DEC 2014 |
| 52.217-5 | Evaluation Of Options | JUL 1990 |
| 52.219-9 (Dev) | Small Business Subcontracting Plan (Deviation 2018-O0018) | JUN 2020 |
| 52.232-33 | Payment by Electronic Funds Transfer--System for Award Management | OCT 2018 |
| 52.232-40 | Providing Accelerated Payments to Small Business Subcontractors | DEC 2013 |
| 52.242-13 | Bankruptcy | JUL 1995 |
| 52.244-5 | Competition In Subcontracting | DEC 1996 |
| 252.203-7000 | Requirements Relating to Compensation of Former DoD Officials | SEP 2011 |
| 252.203-7001 | Prohibition On Persons Convicted of Fraud or Other Defense-Contract-Related Felonies | DEC 2008 |
| 252.203-7003 | Agency Office of the Inspector General | AUG 2019 |

| | | |
|--------------|---|----------|
| 252.204-7002 | Payment For Contract Line or Subline Items Not Separately Priced | APR 2020 |
| 252.204-7006 | Billing Instructions | OCT 2005 |
| 252.204-7012 | Safeguarding Covered Defense Information and Cyber Incident Reporting | DEC 2019 |
| 252.204-7020 | NIST SP 800-171 DoD Assessment Requirements | NOV 2020 |
| 252.225-7048 | Export-Controlled Items | JUN 2013 |
| 252.227-7015 | Technical Data--Commercial Items | FEB 2014 |
| 252.227-7030 | Technical Data--Withholding Of Payment | MAR 2000 |
| 252.227-7037 | Validation of Restrictive Markings on Technical Data | SEP 2016 |
| 252.232-7003 | Electronic Submission of Payment Requests and Receiving Reports | DEC 2018 |
| 252.232-7010 | Levies on Contract Payments | DEC 2006 |
| 252.244-7000 | Subcontracts for Commercial Items | OCT 2020 |

CLAUSES INCORPORATED BY FULL TEXT

52.204-25 PROHIBITION ON CONTRACTING FOR CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUG 2020)

(a) Definitions. As used in this clause--

Backhaul means intermediate links between the core network, or backbone network, and the small subnetworks at the edge of the network (e.g., connecting cell phones/towers to the core telephone network). Backhaul can be wireless (e.g., microwave) or wired (e.g., fiber optic, coaxial cable, Ethernet).

Covered foreign country means The People's Republic of China.

Covered telecommunications equipment or services means--

- (1) Telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities);
- (2) For the purpose of public safety, security of Government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities);
- (3) Telecommunications or video surveillance services provided by such entities or using such equipment; or
- (4) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

Critical technology means--

- (1) Defense articles or defense services included on the United States Munitions List set forth in the International Traffic in Arms Regulations under subchapter M of chapter I of title 22, Code of Federal Regulations;
- (2) Items included on the Commerce Control List set forth in Supplement No. 1 to part 774 of the Export Administration Regulations under subchapter C of chapter VII of title 15, Code of Federal Regulations, and controlled--

- (i) Pursuant to multilateral regimes, including for reasons relating to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology; or
- (ii) For reasons relating to regional stability or surreptitious listening;
- (3) Specially designed and prepared nuclear equipment, parts and components, materials, software, and technology covered by part 810 of title 10, Code of Federal Regulations (relating to assistance to foreign atomic energy activities);
- (4) Nuclear facilities, equipment, and material covered by part 110 of title 10, Code of Federal Regulations (relating to export and import of nuclear equipment and material);
- (5) Select agents and toxins covered by part 331 of title 7, Code of Federal Regulations, part 121 of title 9 of such Code, or part 73 of title 42 of such Code; or
- (6) Emerging and foundational technologies controlled pursuant to section 1758 of the Export Control Reform Act of 2018 (50 U.S.C. 4817).

Interconnection arrangements means arrangements governing the physical connection of two or more networks to allow the use of another's network to hand off traffic where it is ultimately delivered (e.g., connection of a customer of telephone provider A to a customer of telephone company B) or sharing data and other information resources.

Reasonable inquiry means an inquiry designed to uncover any information in the entity's possession about the identity of the producer or provider of covered telecommunications equipment or services used by the entity that excludes the need to include an internal or third-party audit.

Roaming means cellular communications services (e.g., voice, video, data) received from a visited network when unable to connect to the facilities of the home network either because signal coverage is too weak or because traffic is too high.

Substantial or essential component means any component necessary for the proper function or performance of a piece of equipment, system, or service.

(b) Prohibition.

(1) Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. The Contractor is prohibited from providing to the Government any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104.

(2) Section 889(a)(1)(B) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2020, from entering into a contract, or extending or renewing a contract, with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104. This prohibition applies to the use of covered telecommunications equipment or services, regardless of whether that use is in performance of work under a Federal contract.

(c) Exceptions. This clause does not prohibit contractors from providing--

(1) A service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

(2) Telecommunications equipment that cannot route or redirect user data traffic or permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(d) Reporting requirement.

(1) In the event the Contractor identifies covered telecommunications equipment or services used as a substantial or essential component of any system, or as critical technology as part of any system, during contract performance, or the Contractor is notified of such by a subcontractor at any tier or by any other source, the Contractor shall report the information in paragraph (d)(2) of this clause to the Contracting Officer, unless elsewhere in this contract are established procedures for reporting the information; in the case of the Department of Defense, the Contractor shall report to the website at <https://dibnet.dod.mil>. For indefinite delivery contracts, the Contractor shall report to the Contracting Officer for the indefinite delivery contract and the Contracting Officer(s) for any affected order or, in the case of the Department of Defense, identify both the indefinite delivery contract and any affected orders in the report provided at <https://dibnet.dod.mil>.

(2) The Contractor shall report the following information pursuant to paragraph (d)(1) of this clause:

(i) Within one business day from the date of such identification or notification: The contract number; the order number(s), if applicable; supplier name; supplier unique entity identifier (if known); supplier Commercial and Government Entity (CAGE) code (if known); brand; model number (original equipment manufacturer number, manufacturer part number, or wholesaler number); item description; and any readily available information about mitigation actions undertaken or recommended.

(ii) Within 10 business days of submitting the information in paragraph (d)(2)(i) of this clause: Any further available information about mitigation actions undertaken or recommended. In addition, the Contractor shall describe the efforts it undertook to prevent use or submission of covered telecommunications equipment or services, and any additional efforts that will be incorporated to prevent future use or submission of covered telecommunications equipment or services.

(e) Subcontracts. The Contractor shall insert the substance of this clause, including this paragraph (e) and excluding paragraph (b)(2), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial items.

(End of clause)

52.212-4 CONTRACT TERMS AND CONDITIONS-- COMMERCIAL ITEMS (OCT 2018)

(a) Inspection/Acceptance. The Contractor shall only tender for acceptance those items that conform to the requirements of this contract. The Government reserves the right to inspect or test any supplies or services that have been tendered for acceptance. The Government may require repair or replacement of nonconforming supplies or reperformance of nonconforming services at no increase in contract price. If repair/replacement or reperformance will not correct the defects or is not possible, the Government may seek an equitable price reduction or adequate consideration for acceptance of nonconforming supplies or services. The Government must exercise its post-acceptance rights (1) within a reasonable time after the defect was discovered or should have been discovered; and (2) before any substantial change occurs in the condition of the item, unless the change is due to the defect in the item.

(b) Assignment. The Contractor or its assignee may assign its rights to receive payment due as a result of performance of this contract to a bank, trust company, or other financing institution, including any Federal lending agency in accordance with the Assignment of Claims Act (31 U.S.C. 3727). However, when a third party makes payment (e.g., use of the Governmentwide commercial purchase card), the Contractor may not assign its rights to receive payment under this contract.

(c) Changes. Changes in the terms and conditions of this contract may be made only by written agreement of the parties.

(d) Disputes. This contract is subject to 41 U.S.C. chapter 71, "Contract Disputes", as amended (41 U.S.C. 601-613). Failure of the parties to this contract to reach agreement on any request for equitable adjustment, claim, appeal or action arising under or relating to this contract shall be a dispute to be resolved in accordance with the clause at FAR 52.233-1, Disputes, which is incorporated herein by reference. The Contractor shall proceed diligently with performance of this contract, pending final resolution of any dispute arising under the contract.

(e) Definitions. The clause at FAR 52.202-1, Definitions, is incorporated herein by reference.

(f) Excusable delays. The Contractor shall be liable for default unless nonperformance is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence such as, acts of God or the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, unusually severe weather, and delays of common carriers. The Contractor shall notify the Contracting Officer in writing as soon as it is reasonably possible after the commencement or any excusable delay, setting forth the full particulars in connection therewith, shall remedy such occurrence with all reasonable dispatch and shall promptly give written notice to the Contracting Officer of the cessation of such occurrence.

(g) Invoice.

(1) The Contractor shall submit an original invoice and three copies (or electronic invoice, if authorized) to the address designated in the contract to receive invoices. An invoice must include--

(i) Name and address of the Contractor;

(ii) Invoice date and number;

(iii) Contract number, line item number and, if applicable, the order number;

(iv) Description, quantity, unit of measure, unit price and extended price of the items delivered;

(v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on Government bill of lading;

(vi) Terms of any discount for prompt payment offered;

(vii) Name and address of official to whom payment is to be sent;

(viii) Name, title, and phone number of person to notify in event of defective invoice; and

(ix) Taxpayer Identification Number (TIN). The Contractor shall include its TIN on the invoice only if required elsewhere in this contract.

(x) Electronic funds transfer (EFT) banking information.

(A) The Contractor shall include EFT banking information on the invoice only if required elsewhere in this contract.

(B) If EFT banking information is not required to be on the invoice, in order for the invoice to be a proper invoice, the Contractor shall have submitted correct EFT banking information in accordance with the applicable solicitation provision, contract clause (e.g., 52.232-33, Payment by Electronic Funds Transfer—System for Award Management, or 52.232-34, Payment by Electronic Funds Transfer--Other Than System for Award Management), or applicable agency procedures.

(C) EFT banking information is not required if the Government waived the requirement to pay by EFT.

(2) Invoices will be handled in accordance with the Prompt Payment Act (31 U.S.C. 3903) and Office of Management and Budget (OMB) prompt payment regulations at 5 CFR part 1315.

(h) Patent indemnity. The Contractor shall indemnify the Government and its officers, employees and agents against liability, including costs, for actual or alleged direct or contributory infringement of, or inducement to infringe, any United States or foreign patent, trademark or copyright, arising out of the performance of this contract, provided the Contractor is reasonably notified of such claims and proceedings.

(i) Payment.--

(1) Items accepted. Payment shall be made for items accepted by the Government that have been delivered to the delivery destinations set forth in this contract.

(2) Prompt payment. The Government will make payment in accordance with the Prompt Payment Act (31 U.S.C. 3903) and prompt payment regulations at 5 CFR part 1315.

(3) Electronic Funds Transfer (EFT). If the Government makes payment by EFT, see 52.212-5(b) for the appropriate EFT clause.

(4) Discount. In connection with any discount offered for early payment, time shall be computed from the date of the invoice. For the purpose of computing the discount earned, payment shall be considered to have been made on the date which appears on the payment check or the specified payment date if an electronic funds transfer payment is made.

(5) Overpayments. If the Contractor becomes aware of a duplicate contract financing or invoice payment or that the Government has otherwise overpaid on a contract financing or invoice payment, the Contractor shall--

(i) Remit the overpayment amount to the payment office cited in the contract along with a description of the overpayment including the--

(A) Circumstances of the overpayment (e.g., duplicate payment, erroneous payment, liquidation errors, date(s) of overpayment);

(B) Affected contract number and delivery order number, if applicable;

(C) Affected line item or subline item, if applicable; and

(D) Contractor point of contact.

(ii) Provide a copy of the remittance and supporting documentation to the Contracting Officer.

(6) Interest.

(i) All amounts that become payable by the Contractor to the Government under this contract shall bear simple interest from the date due until paid unless paid within 30 days of becoming due. The interest rate shall be the interest rate established by the Secretary of the Treasury as provided in 41 U.S.C.

7109, which is applicable to the period in which the amount becomes due, as provided in (i)(6)(v) of this clause, and then at the rate applicable for each six-month period as fixed by the Secretary until the amount is paid.

(ii) The Government may issue a demand for payment to the Contractor upon finding a debt is due under the contract.

(iii) Final decisions. The Contracting Officer will issue a final decision as required by 33.211 if--

(A) The Contracting Officer and the Contractor are unable to reach agreement on the existence or amount of a debt within 30 days;

(B) The Contractor fails to liquidate a debt previously demanded by the Contracting Officer within the timeline specified in the demand for payment unless the amounts were not repaid because the Contractor has requested an installment payment agreement; or

(C) The Contractor requests a deferment of collection on a debt previously demanded by the Contracting Officer (see 32.607-2).

(iv) If a demand for payment was previously issued for the debt, the demand for payment included in the final decision shall identify the same due date as the original demand for payment.

(v) Amounts shall be due at the earliest of the following dates:

(A) The date fixed under this contract.

(B) The date of the first written demand for payment, including any demand for payment resulting from a default termination.

(vi) The interest charge shall be computed for the actual number of calendar days involved beginning on the due date and ending on--

(A) The date on which the designated office receives payment from the Contractor;

(B) The date of issuance of a Government check to the Contractor from which an amount otherwise payable has been withheld as a credit against the contract debt; or

(C) The date on which an amount withheld and applied to the contract debt would otherwise have become payable to the Contractor.

(vii) The interest charge made under this clause may be reduced under the procedures prescribed in 32.608-2 of the Federal Acquisition Regulation in effect on the date of this contract.

(j) Risk of loss. Unless the contract specifically provides otherwise, risk of loss or damage to the supplies provided under this contract shall remain with the Contractor until, and shall pass to the Government upon:

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

(2) Delivery of the supplies to the Government at the destination specified in the contract, if transportation is f.o.b. destination.

(k) Taxes. The contract price includes all applicable Federal, State, and local taxes and duties.

(l) Termination for the Government's convenience. The Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to

the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor 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 the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

(m) Termination for cause. The Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

(n) Title. Unless specified elsewhere in this contract, title to items furnished under this contract shall pass to the Government upon acceptance, regardless of when or where the Government takes physical possession.

(o) Warranty. The Contractor warrants and implies that the items delivered hereunder are merchantable and fit for use for the particular purpose described in this contract.

(p) Limitation of liability. Except as otherwise provided by an express warranty, the Contractor will not be liable to the Government for consequential damages resulting from any defect or deficiencies in accepted items.

(q) Other compliances. The Contractor shall comply with all applicable Federal, State and local laws, executive orders, rules and regulations applicable to its performance under this contract.

(r) Compliance with laws unique to Government contracts. The Contractor agrees to comply with 31 U.S.C. 1352 relating to limitations on the use of appropriated funds to influence certain Federal contracts; 18 U.S.C. 431 relating to officials not to benefit; 40 U.S.C. chapter 37, Contract Work Hours and Safety Standards; 41 U.S.C. chapter 87, Kickbacks; 41 U.S.C. 4712 and 10 U.S.C. 2409 relating to whistleblower protections; 49 U.S.C. 40118, Fly American; and 41 U.S.C. chapter 21 relating to procurement integrity.

(s) Order of precedence. Any inconsistencies in this solicitation or contract shall be resolved by giving precedence in the following order: (1) the schedule of supplies/services; (2) The Assignments, Disputes, Payments, Invoice, Other Compliances, Compliance with Laws Unique to Government Contracts, and Unauthorized Obligations paragraphs of this clause; (3) the clause at 52.212-5; (4) addenda to this solicitation or contract, including any license agreements for computer software; (5) solicitation provisions if this is a solicitation; (6) other paragraphs of this clause; (7) the Standard Form 1449; (8) other documents, exhibits, and attachments; and (9) the specification.

(t) Reserved.

(u) Unauthorized Obligations.

(1) Except as stated in paragraph (u)(2) of this clause, when any supply or service acquired under this contract is subject to any End User License Agreement (EULA), Terms of Service (TOS), or similar legal instrument or agreement, that includes any clause requiring the Government to indemnify the Contractor or any person or entity for damages, costs, fees, or any other loss or liability that would create an Anti-Deficiency Act violation (31 U.S.C. 1341), the following shall govern:

(i) Any such clause is unenforceable against the Government.

(ii) Neither the Government nor any Government authorized end user shall be deemed to have agreed to such clause by virtue of it appearing in the EULA, TOS, or similar legal instrument or agreement. If the EULA, TOS, or similar

legal instrument or agreement is invoked through an "I agree" click box or other comparable mechanism (e.g., "click-wrap" or "browse-wrap" agreements), execution does not bind the Government or any Government authorized end user to such clause.

(iii) Any such clause is deemed to be stricken from the EULA, TOS, or similar legal instrument or agreement.

(2) Paragraph (u)(1) of this clause does not apply to indemnification by the Government that is expressly authorized by statute and specifically authorized under applicable agency regulations and procedures.

(v) Incorporation by reference. The Contractor's representations and certifications, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract.

(End of Clause)

52.212-5 CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS--COMMERCIAL ITEMS (NOV 2020)

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

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

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

(3) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).

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

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

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

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

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

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

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

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

___ (5) [Reserved]

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

___ (7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).

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

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

___ (10) [Reserved]

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

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

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

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

___ (13) [Reserved]

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

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

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

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

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

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

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

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

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

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

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

___ (ii) Alternate I (MAR 2020) of 52.219-13.

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

- ___ (20) 52.219-16, Liquidated Damages—Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).
- ___ (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (MAR 2020) (15 U.S.C. 657f).
- XX (22) (i) 52.219-28, Post Award Small Business Program Rerepresentation (NOV 2020) (15 U.S.C. 632(a)(2)).
- ___ (ii) Alternate I (MAR 2020) of 52.219-28.
- ___ (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business (EDWOSB) Concerns (MAR 2020) (15 U.S.C. 637(m)).
- ___ (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (MAR 2020) (15 U.S.C. 637(m)).
- ___ (25) 52.219-32, Orders Issued Directly Under Small Business Reserves (MAR 2020) (15 U.S.C. 644(r)).
- ___ (26) 52.219-33, Nonmanufacturer Rule (MAR 2020) (15 U.S.C. 637(a)(17)).
- XX (27) 52.222-3, Convict Labor (JUN 2003) (E.O. 11755).
- XX (28) 52.222-19, Child Labor--Cooperation with Authorities and Remedies (JAN 2020) (E.O. 13126).
- XX (29) 52.222-21, Prohibition of Segregated Facilities (APR 2015).
- XX (30)(i) 52.222-26, Equal Opportunity (SEPT 2016) (E.O. 11246).
- ___ (ii) Alternate I (FEB 1999) of 52.222-26.
- XX (31)(i) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).
- ___ (ii) Alternate I (JUL 2014) of 52.222-35.
- XX (32)(i) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).
- ___ (ii) Alternate I (JUL 2014) of 52.222-36.
- XX (33) 52.222-37, Employment Reports on Veterans (JUN 2020) (38 U.S.C. 4212).
- XX (34) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496).
- XX (35)(i) 52.222-50, Combating Trafficking in Persons (OCT 2020) (22 U.S.C. chapter 78 and E.O. 13627).
- ___ (ii) Alternate I (MAR 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
- XX (36) 52.222-54, Employment Eligibility Verification (OCT 2015). (E. O. 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)
- ___ (37)(i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA–Designated Items (MAY 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

____ (ii) Alternate I (MAY 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

____ (38) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (JUN 2016) (E.O. 13693).

____ (39) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (JUN 2016) (E.O. 13693).

____ (40) (i) 52.223-13, Acquisition of EPEAT® Registered Imaging Equipment (JUN 2014) (E.O.s 13423 and 13514).

____ (ii) Alternate I (OCT 2015) of 52.223-13.

____ (41)(i) 52.223-14, Acquisition of EPEAT® Registered Televisions (JUN 2014) (E.O.s 13423 and 13514).

____ (ii) Alternate I (JUN 2014) of 52.223-14.

____ (42) 52.223-15, Energy Efficiency in Energy-Consuming Products (MAY 2020) (42 U.S.C. 8259b).

____ (43)(i) 52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products (OCT 2015) (E.O.s 13423 and 13514).

____ (ii) Alternate I (JUN 2014) of 52.223-16.

XX (44) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (JUN 2020) (E.O. 13513).

____ (45) 52.223-20, Aerosols (JUN 2016) (E.O. 13693).

____ (46) 52.223-21, Foams (JUN 2016) (E.O. 13693).

____ (47)(i) 52.224-3, Privacy Training (JAN 2017) (5 U.S.C. 552a).

____ (ii) Alternate I (JAN 2017) of 52.224-3.

____ (48) 52.225-1, Buy American--Supplies (MAY 2014) (41 U.S.C. chapter 83).

____ (49) (i) 52.225-3, Buy American--Free Trade Agreements--Israeli Trade Act (MAY 2014) (41 U.S.C. chapter 83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43).

____ (ii) Alternate I (MAY 2014) of 52.225-3.

____ (iii) Alternate II (MAY 2014) of 52.225-3.

____ (iv) Alternate III (MAY 2014) of 52.225-3.

____ (50) 52.225-5, Trade Agreements (OCT 2019) 19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).

XX (51) 52.225-13, Restrictions on Certain Foreign Purchases (JUN 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

____ (52) 52.225-26, Contractors Performing Private Security Functions Outside the United States (OCT 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).

- ____ (53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (NOV 2007) (42 U.S.C. 5150)
- ____ (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (NOV 2007) (42 U.S.C. 5150).
- ____ (55) 52.229-12, Tax on Certain Foreign Procurements (JUN 2020).
- ____ (56) 52.232-29, Terms for Financing of Purchases of Commercial Items (FEB 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
- ____ (57) 52.232-30, Installment Payments for Commercial Items (JAN 2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
- XX (58) 52.232-33, Payment by Electronic Funds Transfer—System for Award Management (OCT 2018) (31 U.S.C. 3332).
- ____ (59) 52.232-34, Payment by Electronic Funds Transfer—Other than System for Award Management (JUL 2013) (31 U.S.C. 3332).
- ____ (60) 52.232-36, Payment by Third Party (MAY 2014) (31 U.S.C. 3332).
- ____ (61) 52.239-1, Privacy or Security Safeguards (AUG 1996) (5 U.S.C. 552a).
- XX (62) 52.242-5, Payments to Small Business Subcontractors (JAN 2017)(15 U.S.C. 637(d)(13)).
- ____ (63)(i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (FEB 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).
- ____ (ii) Alternate I (APR 2003) of 52.247-64.
- ____ (iii) Alternate II (FEB 2006) of 52.247-64.
- (c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items: (Contracting Officer check as appropriate.)
- ____ (1) 52.222-41, Service Contract Labor Standards (AUG 2018) (41 U.S.C. chapter 67).
- ____ (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (MAY 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
- ____ (3) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards--Price Adjustment (Multiple Year and Option Contracts) (AUG 2018) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
- ____ (4) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards--Price Adjustment (MAY 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
- ____ (5) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (MAY 2014) (41 U.S.C. chapter 67).
- ____ (6) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements (MAY 2014) (41 U.S.C. chapter 67).
- ____ (7) 52.222-55, Minimum Wages Under Executive Order 13658 (NOV 2020) (E.O. 13658).

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

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

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

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

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

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

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

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

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

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

(iv) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).

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

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

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

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

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

- (x) 52.222-37, Employment Reports on Veterans (JUN 2020) (38 U.S.C. 4212).
- (xi) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.
- (xii) 52.222-41, Service Contract Labor Standards (Aug 2018), (41 U.S.C. chapter 67).
- (xiii) _____ (A) 52.222-50, Combating Trafficking in Persons (OCT 2020) (22 U.S.C. chapter 78 and E.O. 13627).
_____ (B) Alternate I (March 2, 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
- (xiv) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (May 2014) (41 U.S.C. chapter 67.)
- (xv) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements (May 2014) (41 U.S.C. chapter 67)
- (xvi) 52.222-54, Employment Eligibility Verification (Oct 2015) (E. O. 12989).
- (xvii) 52.222-55, Minimum Wages Under Executive Order 13658 (NOV 2020) (E.O. 13658).
- (xviii) [52.222-62](#), Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).
- (xix) (A) [52.224-3](#), Privacy Training (Jan 2017) ([5 U.S.C. 552a](#)).
(B) Alternate I (Jan 2017) of [52.224-3](#).
- (xx) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
- (xxi) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations. (JUN 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.
- (xxii) 52.247-64, Preference for Privately-Owned U.S. Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.
- (2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)

52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)

- (a) The Government may extend the term of this contract by written notice to the Contractor within 15 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.
- (b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 20.5 months.

(End of clause)

52.252-6 AUTHORIZED DEVIATIONS IN CLAUSES (NOV 2020)

(a) The use in this solicitation or contract of any Federal Acquisition Regulation (48 CFR Chapter 1) clause with an authorized deviation is indicated by the addition of "(DEVIATION)" after the date of the clause.

(b) The use in this solicitation or contract of any Defense Federal Acquisition Regulation Supplement (48 CFR Chapter 2) clause with an authorized deviation is indicated by the addition of "(DEVIATION)" after the name of the regulation.

(End of clause)

252.227-7013 RIGHTS IN TECHNICAL DATA--NONCOMMERCIAL ITEMS (FEB 2014)

(a) Definitions. As used in this clause--

(1) Computer data base means a collection of data recorded in a form capable of being processed by a computer. The term does not include computer software.

(2) Computer program means a set of instructions, rules, or routines recorded in a form that is capable of causing a computer to perform a specific operation or series of operations.

(3) Computer software means computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae and related material that would enable the software to be reproduced, recreated, or recompiled. Computer software does not include computer data bases or computer software documentation.

(4) Computer software documentation means owner's manuals, user's manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.

(5) Covered Government support contractor means a contractor (other than a litigation support contractor covered by 252.204-7014) under a contract, the primary purpose of which is to furnish independent and impartial advice or technical assistance directly to the Government in support of the Government's management and oversight of a program or effort (rather than to directly furnish an end item or service to accomplish a program or effort), provided that the contractor--

(i) Is not affiliated with the prime contractor or a first-tier subcontractor on the program or effort, or with any direct competitor of such prime contractor or any such first-tier subcontractor in furnishing end items or services of the type developed or produced on the program or effort; and

(ii) Receives access to technical data or computer software for performance of a Government contract that contains the clause at 252.227-7025, Limitations on the Use or Disclosure of Government-Furnished Information Marked with Restrictive Legends.

(6) Detailed manufacturing or process data means technical data that describe the steps, sequences, and conditions of manufacturing, processing or assembly used by the manufacturer to produce an item or component or to perform a process.

(7) Developed means that an item, component, or process exists and is workable. Thus, the item or component must have been constructed or the process practiced. Workability is generally established when the item, component, or process has been analyzed or tested sufficiently to demonstrate to reasonable people skilled in the applicable art that there is a high probability that it will operate as intended. Whether, how much, and what type of analysis or testing is required to establish workability depends on the nature of the item, component, or process, and the state of the art. To be considered "developed," the item, component, or process need not be at the stage where it could be offered for sale or sold on the commercial market, nor must the item, component, or process be actually reduced to practice within the meaning of Title 35 of the United States Code.

(8) Developed exclusively at private expense means development was accomplished entirely with costs charged to indirect cost pools, costs not allocated to a government contract, or any combination thereof.

(i) Private expense determinations should be made at the lowest practicable level.

(ii) Under fixed-price contracts, when total costs are greater than the firm-fixed-price or ceiling price of the contract, the additional development costs necessary to complete development shall not be considered when determining whether development was at government, private, or mixed expense.

(9) Developed exclusively with government funds means development was not accomplished exclusively or partially at private expense.

(10) Developed with mixed funding means development was accomplished partially with costs charged to indirect cost pools and/or costs not allocated to a government contract, and partially with costs charged directly to a government contract.

(11) Form, fit, and function data means technical data that describes the required overall physical, functional, and performance characteristics (along with the qualification requirements, if applicable) of an item, component, or process to the extent necessary to permit identification of physically and functionally interchangeable items.

(12) Government purpose means any activity in which the United States Government is a party, including cooperative agreements with international or multi-national defense organizations, or sales or transfers by the United States Government to foreign governments or international organizations. Government purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose technical data for commercial purposes or authorize others to do so.

(13) Government purpose rights means the rights to--

(i) Use, modify, reproduce, release, perform, display, or disclose technical data within the Government without restriction; and

(ii) Release or disclose technical 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 United States government purposes.

(14) Limited rights means the rights to use, modify, reproduce, release, perform, display, or disclose technical data, in whole or in part, within the Government. The Government may not, without the written permission of the party asserting limited rights, release or disclose the technical data outside the Government, use the technical data for manufacture, or authorize the technical data to be used by another party, except that the Government may reproduce, release, or disclose such data or authorize the use or reproduction of the data by persons outside the Government if--

(i) The reproduction, release, disclosure, or use is--

(A) Necessary for emergency repair and overhaul; or

(B) A release or disclosure to--

(1) A covered Government support contractor in performance of its covered Government support contract for use, modification, reproduction, performance, display, or release or disclosure to a person authorized to receive limited rights technical data; or

(2) A foreign government, of technical data other than detailed manufacturing or process data, when use of such data by the foreign government is in the interest of the Government and is required for evaluational or informational purposes;

(ii) The recipient of the technical data is subject to a prohibition on the further reproduction, release, disclosure, or use of the technical data; and

(iii) The contractor or subcontractor asserting the restriction is notified of such reproduction, release, disclosure, or use.

(15) Technical data means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information.

(16) Unlimited rights means rights to use, modify, reproduce, perform, display, release, or disclose technical data in whole or in part, in any manner, and for any purpose whatsoever, and to have or authorize others to do so.

(b) Rights in technical data. The Contractor grants or shall obtain for the Government the following royalty free, world-wide, nonexclusive, irrevocable license rights in technical data other than computer software documentation (see the Rights in Noncommercial Computer Software and Noncommercial Computer Software Documentation clause of this contract for rights in computer software documentation):

(1) Unlimited rights.

The Government shall have unlimited rights in technical data that are--

(i) Data pertaining to an item, component, or process which has been or will be developed exclusively with Government funds;

(ii) Studies, analyses, test data, or similar data produced for this contract, when the study, analysis, test, or similar work was specified as an element of performance;

(iii) Created exclusively with Government funds in the performance of a contract that does not require the development, manufacture, construction, or production of items, components, or processes;

(iv) Form, fit, and function data;

(v) Necessary for installation, operation, maintenance, or training purposes (other than detailed manufacturing or process data);

(vi) Corrections or changes to technical data furnished to the Contractor by the Government;

(vii) Otherwise publicly available or have been released or disclosed by the Contractor or subcontractor 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 technical data to another party or the sale or transfer of some or all of a business entity or its assets to another party;

- (viii) Data in which the Government has obtained unlimited rights under another Government contract or as a result of negotiations; or
- (ix) Data furnished to the Government, under this or any other Government contract or subcontract thereunder, with-
-
- (A) Government purpose license rights or limited rights and the restrictive condition(s) has/have expired; or
- (B) Government purpose rights and the Contractor's exclusive right to use such data for commercial purposes has expired.
- (2) Government purpose rights.
- (i) The Government shall have government purpose rights for a five-year period, or such other period as may be negotiated, in technical data--
- (A) That pertain to items, components, or processes developed with mixed funding except when the Government is entitled to unlimited rights in such data as provided in paragraphs as provided in paragraphs (b)(1)(ii) and (b)(1)(iv) through (b)(1)(ix) of this clause; or
- (B) Created with mixed funding in the performance of a contract that does not require the development, manufacture, construction, or production of items, components, or processes.
- (ii) The five-year period, or such other period as may have been negotiated, shall commence upon execution of the contract, subcontract, letter contract (or similar contractual instrument), contract modification, or option exercise that required development of the items, components, or processes or creation of the data described in paragraph (b)(2)(i)(B) of this clause. Upon expiration of the five-year or other negotiated period, the Government shall have unlimited rights in the technical data.
- (iii) The Government shall not release or disclose technical data in which it has government purpose rights unless-
- (A) Prior to release or disclosure, the intended recipient is subject to the non-disclosure agreement at 227.7103-7 of the Defense Federal Acquisition Regulation Supplement (DFARS); or
- (B) The recipient is a Government contractor receiving access to the data for performance of a Government contract that contains the clause at DFARS 252.227-7025, Limitations on the Use or Disclosure of Government-Furnished Information Marked with Restrictive Legends.
- (iv) The Contractor has the exclusive right, including the right to license others, to use technical data in which the Government has obtained government purpose rights under this contract for any commercial purpose during the time period specified in the government purpose rights legend prescribed in paragraph (f)(2) of this clause.
- (3) Limited rights.
- (i) Except as provided in paragraphs (b)(1)(ii) and (b)(1)(iv) through (b)(1)(ix) of this clause, the Government shall have limited rights in technical data--
- (A) Pertaining to items, components, or processes developed exclusively at private expense and marked with the limited rights legend prescribed in paragraph (f) of this clause; or
- (B) Created exclusively at private expense in the performance of a contract that does not require the development, manufacture, construction, or production of items, components, or processes.

(ii) The Government shall require a recipient of limited rights data for emergency repair or overhaul to destroy the data and all copies in its possession promptly following completion of the emergency repair/overhaul and to notify the Contractor that the data have been destroyed.

(iii) The Contractor, its subcontractors, and suppliers are not required to provide the Government additional rights to use, modify, reproduce, release, perform, display, or disclose technical data furnished to the Government with limited rights. However, if the Government desires to obtain additional rights in technical data in which it has limited rights, the Contractor agrees to promptly enter into negotiations with the Contracting Officer to determine whether there are acceptable terms for transferring such rights. All technical data in which the Contractor has granted the Government additional rights shall be listed or described in a license agreement made part of the contract. The license shall enumerate the additional rights granted the Government in such data.

(iv) The Contractor acknowledges that--

(A) Limited rights data are authorized to be released or disclosed to covered Government support contractors;

(B) The Contractor will be notified of such release or disclosure;

(C) The Contractor (or the party asserting restrictions as identified in the limited rights legend) may require each such covered Government support contractor to enter into a non-disclosure agreement directly with the Contractor (or the party asserting restrictions) regarding the covered Government support contractor's use of such data, or alternatively, that the Contractor (or party asserting restrictions) may waive in writing the requirement for a non-disclosure agreement; and

(D) Any such non-disclosure agreement shall address the restrictions on the covered Government support contractor's use of the limited rights data as set forth in the clause at 252.227-7025, Limitations on the Use or Disclosure of Government-Furnished Information Marked with Restrictive Legends. The non-disclosure agreement shall not include any additional terms and conditions unless mutually agreed to by the parties to the non-disclosure agreement.

(E) The Contractor shall provide a copy of any such non-disclosure agreement or waiver to the Contracting Officer, upon request.

(4) Specifically negotiated license rights.

The standard license rights granted to the Government under paragraphs (b)(1) through (b)(3) of this clause, including the period during which the Government shall have government purpose rights in technical data, may be modified by mutual agreement to provide such rights as the parties consider appropriate but shall not provide the Government lesser rights than are enumerated in paragraph (a)(14) of this clause. Any rights so negotiated shall be identified in a license agreement made part of this contract.

(5) Prior government rights.

Technical data that will be delivered, furnished, or otherwise provided to the Government under this contract, in which the Government has previously obtained rights shall be delivered, furnished, or provided with the pre-existing rights, unless--

(i) The parties have agreed otherwise; or

(ii) Any restrictions on the Government's rights to use, modify, reproduce, release, perform, display, or disclose the data have expired or no longer apply.

(6) Release from liability.

The Contractor agrees to release the Government from liability for any release or disclosure of technical data made in accordance with paragraph (a)(14) or (b)(2)(iii) of this clause, in accordance with the terms of a license negotiated under paragraph (b)(4) of this clause, or by others to whom the recipient has released or disclosed the data and to seek relief solely from the party who has improperly used, modified, reproduced, released, performed, displayed, or disclosed Contractor data marked with restrictive legends.

(c) Contractor rights in technical data. All rights not granted to the Government are retained by the Contractor.

(d) Third party copyrighted data. The Contractor shall not, without the written approval of the Contracting Officer, incorporate any copyrighted data in the technical data to be delivered under this contract unless the Contractor is the copyright owner or has obtained for the Government the license rights necessary to perfect a license or licenses in the deliverable data of the appropriate scope set forth in paragraph (b) of this clause, and has affixed a statement of the license or licenses obtained on behalf of the Government and other persons to the data transmittal document.

(e) Identification and delivery of data to be furnished with restrictions on use, release, or disclosure. (1) This paragraph does not apply to restrictions based solely on copyright.

(2) Except as provided in paragraph (e)(3) of this clause, technical data that the Contractor asserts should be furnished to the Government with restrictions on use, release, or disclosure are identified in an attachment to this contract (the Attachment). The Contractor shall not deliver any data with restrictive markings unless the data are listed on the Attachment.

(3) In addition to the assertions made in the Attachment, other assertions may be identified after award when based on new information or inadvertent omissions unless the inadvertent omissions would have materially affected the source selection decision. Such identification and assertion shall be submitted to the Contracting Officer as soon as practicable prior to the scheduled date for delivery of the data, in the following format, and signed by an official authorized to contractually obligate the Contractor: Identification and Assertion of Restrictions on the Government's Use, Release, or Disclosure of Technical Data.

The Contractor asserts for itself, or the persons identified below, that the Government's rights to use, release, or disclose the following technical data should be restricted--

| Technical data to be Furnished With Restrictions \1/ | Basis for Assertion \2/ | Asserted Rights Category \3/ | Name of Person Asserting Restrictions \4/ |
|--|-------------------------|------------------------------|---|
| (LIST) | (LIST) | (LIST) | (LIST) |

\1/ If the assertion is applicable to items, components or processes developed at private expense, identify both the data and each such items, component, or process.

\2/ Generally, the development of an item, component, or process at private expense, either exclusively or partially, is the only basis for asserting restrictions on the Government's rights to use, release, or disclose technical data pertaining to such items, components, or processes. Indicate whether development was exclusively or partially at private expense. If development was not at private expense, enter the specific reason for asserting that the Government's rights should be restricted.

\3/ Enter asserted rights category (e.g., government purpose license rights from a prior contract, rights in SBIR data generated under another contract, limited or government purpose rights under this or a prior contract, or specifically negotiated licenses).

\4/ Corporation, individual, or other person, as appropriate.

Date _____

Printed Name and Title _____

Signature _____

(End of identification and assertion)

(4) When requested by the Contracting Officer, the Contractor shall provide sufficient information to enable the Contracting Officer to evaluate the Contractor's assertions. The Contracting Officer reserves the right to add the Contractor's assertions to the Attachment and validate any listed assertion, at a later date, in accordance with the procedures of the Validation of Restrictive Markings on Technical Data clause of this contract.

(f) Marking requirements. The Contractor, and its subcontractors or suppliers, may only assert restrictions on the Government's rights to use, modify, reproduce, release, perform, display, or disclose technical data to be delivered under this contract by marking the deliverable data subject to restriction. Except as provided in paragraph (f)(5) of this clause, only the following legends are authorized under this contract: the government purpose rights legend at paragraph (f)(2) of this clause; the limited rights legend at paragraph (f)(3) of this clause; or the special license rights legend at paragraph (f)(4) of this clause; and/or a notice of copyright as prescribed under 17 U.S.C. 401 or 402.

(1) General marking instructions. The Contractor, or its subcontractors or suppliers, shall conspicuously and legibly mark the appropriate legend on all technical data that qualify for such markings. The authorized legends shall be placed on the transmittal document or storage container and, for printed material, each page of the printed material containing technical data for which restrictions are asserted. When only portions of a page of printed material are subject to the asserted restrictions, such portions shall be identified by circling, underscoring, with a note, or other appropriate identifier. Technical data transmitted directly from one computer or computer terminal to another shall contain a notice of asserted restrictions. Reproductions of technical data or any portions thereof subject to asserted restrictions shall also reproduce the asserted restrictions.

(2) Government purpose rights markings. Data delivered or otherwise furnished to the Government purpose rights shall be marked as follows:

Government Purpose Rights

Contract No. _____

Contractor Name _____

Contractor Address _____

Expiration Date _____

The Government's rights to use, modify, reproduce, release, perform, display, or disclose these technical data are restricted by paragraph (b)(2) of the Rights in Technical Data--Noncommercial Items clause contained in the above identified contract. No restrictions apply after the expiration date shown above. Any reproduction of technical data or portions thereof marked with this legend must also reproduce the markings.

(End of legend)

(3) Limited rights markings. Data delivered or otherwise furnished to the Government with limited rights shall be marked with the following legend:

Limited Rights

Contract No. _____

Contractor Name _____

Contractor Address _____

The Government's rights to use, modify, reproduce, release, perform, display, or disclose these technical data are restricted by paragraph (b)(3) of the Rights in Technical Data--Noncommercial Items clause contained in the above identified contract. Any reproduction of technical data or portions thereof marked with this legend must also reproduce the markings. Any person, other than the Government, who has been provided access to such data must promptly notify the above named Contractor.

(End of legend)

(4) Special license rights markings. (i) Data in which the Government's rights stem from a specifically negotiated license shall be marked with the following legend:

Special License Rights

The Government's rights to use, modify, reproduce, release, perform, display, or disclose these data are restricted by Contract No. _____ (Insert contract number) _____, License No. _____ (Insert license identifier) _____. Any reproduction of technical data or portions thereof marked with this legend must also reproduce the markings.

(End of legend)

(ii) For purposes of this clause, special licenses do not include government purpose license rights acquired under a prior contract (see paragraph (b)(5) of this clause).

(5) Pre-existing data markings. If the terms of a prior contract or license permitted the Contractor to restrict the Government's rights to use, modify, reproduce, release, perform, display, or disclose technical data deliverable under this contract, and those restrictions are still applicable, the Contractor may mark such data with the appropriate restrictive legend for which the data qualified under the prior contract or license. The marking procedures in paragraph (f)(1) of this clause shall be followed.

(g) Contractor procedures and records. Throughout performance of this contract, the Contractor and its subcontractors or suppliers that will deliver technical data with other than unlimited rights, shall--

(1) Have, maintain, and follow written procedures sufficient to assure that restrictive markings are used only when authorized by the terms of this clause; and

(2) Maintain records sufficient to justify the validity of any restrictive markings on technical data delivered under this contract.

(h) Removal of unjustified and nonconforming markings. (1) Unjustified technical data markings. The rights and obligations of the parties regarding the validation of restrictive markings on technical data furnished or to be furnished under this contract are contained in the Validation of Restrictive Markings on Technical Data clause of this contract. Notwithstanding any provision of this contract concerning inspection and acceptance, the Government may ignore or, at the Contractor's expense, correct or strike a marking if, in accordance with the procedures in the Validation of Restrictive Markings on Technical Data clause of this contract, a restrictive marking is determined to be unjustified.

(2) Nonconforming technical data markings. A nonconforming marking is a marking placed on technical data delivered or otherwise furnished to the Government under this contract that is not in the format authorized by this contract. Correction of nonconforming markings is not subject to the validation of Restrictive Markings on Technical Data clause of this contract. If the Contracting Officer notifies the Contractor of a nonconforming marking and the Contractor fails to remove or correct such marking within sixty (60) days, the Government may ignore or, at the Contractor's expense, remove or correct any nonconforming marking.

(i) Relation to patents. Nothing contained in this clause shall imply a license to the Government under any patent or be construed as affecting the scope of any license or other right otherwise granted to the Government under any patent.

(j) Limitation on charges for rights in technical data. (1) The Contractor shall not charge to this contract any cost, including, but not limited to, license fees, royalties, or similar charges, for rights in technical data to be delivered under this contract when--

(i) The Government has acquired, by any means, the same or greater rights in the data; or

(ii) The data are available to the public without restrictions.

(2) The limitation in paragraph (j)(1) of this clause--

(i) Includes costs charged by a subcontractor or supplier, at any tier, or costs incurred by the Contractor to acquire rights in subcontractor or supplier technical data, if the subcontractor or supplier has been paid for such rights under any other Government contract or under a license conveying the rights to the Government; and

(ii) Does not include the reasonable costs of reproducing, handling, or mailing the documents or other media in which the technical data will be delivered.

(k) Applicability to subcontractors or suppliers. (1) The Contractor shall ensure that the rights afforded its subcontractors and suppliers under 10 U.S.C. 2320, 10 U.S.C. 2321, and the identification, assertion, and delivery processes of paragraph (e) of this clause are recognized and protected.

(2) Whenever any technical data for noncommercial items, or for commercial items developed in any part at Government expense, is to be obtained from a subcontractor or supplier for delivery to the Government under this contract, the Contractor shall use this same clause in the subcontract or other contractual instrument, including subcontracts or other contractual instruments for commercial items, and requires subcontractors or suppliers to do so, without alteration, except to identify the parties. This clause will govern the technical data pertaining to noncommercial items or to any portion of a commercial item that was developed in any part at Government expense, and the clause at 252.227-7015 will govern the technical data pertaining to any portion of a commercial item that was developed exclusively at private expense. No other clause shall be used to enlarge or diminish the Government's, the Contractor's, or a higher-tier subcontractor's or supplier's rights in a subcontractor's or supplier's technical data.

(3) Technical data required to be delivered by a subcontractor or supplier shall normally be delivered to the next higher-tier contractor, subcontractor, or supplier. However, when there is a requirement in the prime contract for data which may be submitted with other than unlimited rights by a subcontractor or supplier, then said subcontractor or supplier may fulfill its requirement by submitting such data directly to the Government, rather than through a higher-tier contractor, subcontractor, or supplier.

(4) The Contractor and higher-tier subcontractors or suppliers shall not use their power to award contracts as economic leverage to obtain rights in technical data from their subcontractors or suppliers. (5) In no event shall the Contractor use its obligation to recognize and protect subcontractor or supplier rights in technical data as an excuse for failing to satisfy its contractual obligations to the Government.

(End of clause)

LIST OF ATTACHMENTS & EXHIBITS

| | Title | # of Pages | Date |
|-----------------|-----------------------|-------------------|-----------------|
| Exhibit A | CDRLs | 32 | 20 May 2021 |
| Attachment 0001 | Security Requirements | 6 | 11 October 2020 |
| Attachment 0002 | Data Rights | 2 | 2 June 2021 |

Exhibit A
Contract Data Requirements List

| Data Item # | Title of Data Item | Date |
|--------------------|---|-------------|
| A001 | Post Award Teleconference | 20 May 2021 |
| A002 | Kickoff Meeting | 20 May 2021 |
| A003 | Teleconference Minutes | 20 May 2021 |
| A004 | Quarterly Meetings | 20 May 2021 |
| A005 | FDA Meeting Minutes | 20 May 2021 |
| A006 | Daily check in with project staff for COVID-19 Contract | 20 May 2021 |
| A007 | Monthly Progress Reports | 20 May 2021 |
| A008 | Draft Technical Progress Report | 20 May 2021 |
| A009 | Final Technical Progress Report | 20 May 2021 |
| A010 | Product Development Source Material and Manufacturing Reports | 20 May 2021 |
| A011 | Contractor Locations | 20 May 2021 |
| A012 | Pandemic Management Plan | 20 May 2021 |
| A013 | Supply Chain and Distribution Tracking. Distribution Concept of Operations. | 20 May 2021 |
| A014 | Distribution Plan | 20 May 2021 |
| A015 | Distribution Memorandum of Understanding | 20 May 2021 |
| A016 | Manufacturing Development Plan | 20 May 2021 |
| A017 | Quality Management Plan | 20 May 2021 |
| A018 | Quality Agreement | 20 May 2021 |
| A019 | Release documentation for doses to be delivered | 20 May 2021 |
| A020 | Security Plan | 20 May 2021 |
| A021 | Supply Chain Resiliency Plan | 20 May 2021 |
| A022 | Manufacturing Data Requirements | 20 May 2021 |
| A023 | BARDA Audit | 20 May 2021 |
| A024 | FDA Inspections | 20 May 2021 |
| A025 | QA Audits | 20 May 2021 |
| A026 | Integrated Master Schedule | 20 May 2021 |
| A027 | Deviation Notification and Mitigation Strategy | 20 May 2021 |
| A028 | Incident Report | 20 May 2021 |
| A029 | FDA Correspondence and Submissions | 20 May 2021 |
| A030 | Provision of Public Law 115-92 Sponsor Authorization Letter | 20 May 2021 |
| A031 | Press Releases | 20 May 2021 |
| A032 | Educational Materials | 20 May 2021 |

W911QY-21-C-0031
Attachment 0002
Data Rights

Date: 2 June 2021
of pages: 2

| Data Item # | Title of Data Item | Data Rights Assertion ¹ |
|-------------|---|------------------------------------|
| A001 | Post Award Teleconference | (b) (4) |
| A002 | Kickoff Meeting | |
| A003 | Teleconference Minutes | |
| A004 | Quarterly Meetings | |
| A005 | FDA Meeting Minutes | |
| A006 | Daily check in with project staff for COVID-19 Contract | |
| A007 | Monthly Progress Reports | |
| A008 | Draft Technical Progress Report | |
| A009 | Final Technical Progress Report | |
| A010 | Product Development Source Material and Manufacturing Reports | |
| A011 | Contractor Locations | |
| A012 | Pandemic Management Plan | |
| A013 | Supply Chain and Distribution Tracking. Distribution Concept of Operations. | |
| A014 | Distribution Plan | |
| A015 | Distribution Memorandum of Understanding | |
| A016 | Manufacturing Development Plan | |
| A017 | Quality Management Plan | |
| A018 | Quality Agreement | |
| A019 | Release documentation for doses to be delivered | |
| A020 | Security Plan | |
| A021 | Supply Chain Resiliency Plan | |

¹ Data rights assertions are according to the definitions of DFARS 252.227-7013.

² (b) (4)

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| A022 | Manufacturing Data Requirements | (b) (4) |
| A023 | BARDA Audit | |
| A024 | FDA Inspections | |
| A025 | QA Audits | |
| A026 | Integrated Master Schedule | |
| A027 | Deviation Notification and Mitigation Strategy | |
| A028 | Incident Report | |
| A029 | FDA Correspondence and Submissions | |
| A030 | Provision of Public Law 115-92 Sponsor Authorization Letter | |
| A031 | Press Releases | |
| A032 | Educational Materials | |

W911QY-21-C-0031
Exhibit A
Contract Data Requirements List
CDRLs

Date: 20 May 2021
of pages: 33

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved
OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 110 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____ |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A001 | 2. TITLE OF DATA ITEM Post Award Teleconference Minutes | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DI-ADMN-81505 | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | b. COPIES | |
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| <p>16. REMARKS</p> <p>The Awardee shall complete an initial teleconference after agreement award</p> <ol style="list-style-type: none"> Outline activities for the next 30 days Discuss agenda items for the post-award Kickoff Meeting (A002) <p>Within one week of Agreement award</p> <ul style="list-style-type: none"> Awardee shall provide agenda and establish a teleconference number at least 3 business days in advance of the teleconference unless notified that BARDA will supply one AOR edits/approves and instructs Awardee to distribute agenda prior to meeting by at least 2 business days Awardee provides meeting minutes to AOR within 3 business days after the meeting AOR reviews, comments and approves minutes within 10 business days | BARDA | 1 | | |
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| 17. PRICE GROUP |
| 18. ESTIMATED TOTAL PRICE |

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| G. PREPARED BY (b) (6) [Redacted] Date: 2021.05.20 13:59:39 -0400 | H. DATE | I. APPROVED BY (b) (6) [Redacted] S Date: 2021.05.20 13:59:39 -0400 | J. DATE |
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CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____ |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A002 | 2. TITLE OF DATA ITEM Kickoff Meeting Agenda and Minutes | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DI-ADMN-81505 | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | b. COPIES | | |
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| 16. REMARKS The Awardee shall complete a Kickoff meeting after agreement award • Within a month of agreement award, pending concurrence by the agreements officer • Awardee shall provide itinerary and agenda at least 5 business days in advance of site visit or virtual meeting • AOR edits/approves and instructs Awardee to distribute agenda prior to meeting by at least 3 business days • Awardee provides meeting minutes to AOR within 3 business days after the meeting • AOR reviews, comments, and approves minutes within 10 business days | BARDA | 1 | | | |
| | JPEO CBRND | 1 | | | |
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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

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CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 110 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____ |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A003 | 2. TITLE OF DATA ITEM Teleconference Minutes | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DI-ADMN-81505 | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | b. COPIES | | |
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16. REMARKS

The Awardee shall participate in teleconferences every 2 weeks, with BARDA to discuss the performance on the Agreement. Meeting frequency can be increased or decreased with agreement between both parties as needed during the course of the project • Awardee provides agenda to AOR no later than 2 business days in advance of meeting

- AOR edits/approves and instructs Awardee to distribute agenda prior to meeting
- Awardee distributes agenda and presentation materials if needed at least 24 hours in advance
- Awardee provides meeting minutes to AOR within 5 business days of the meeting
- AOR reviews, comments, and approves minutes within 6 business days
- Updates to include distribution and regulatory issues

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17. PRICE GROUP

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CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved
OMB No. 0704-0188

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM <input type="checkbox"/> OTHER <input type="checkbox"/> |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A004 | 2. TITLE OF DATA ITEM Quarterly Meetings | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DI-ADMN-81505 | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | b. COPIES | |
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| 16. REMARKS At the discretion of the government the Awardee shall hold recurring teleconference. The meetings will be used to discuss agreement progress in relation to the Program Management deliverables described below as well as study designs, technical, regulatory, and ethical aspects of the program. <ul style="list-style-type: none"> • Awardee shall provide itinerary and agenda at least 5 business days, and presentation materials at least 3 business days in advance of site visit • AOR edits/approves and instructs Awardee to distribute agenda prior to meeting by at least 3 business days • Awardee provides meeting minutes to AOR within 3 business days after the meeting • AOR reviews, comments, and approves minutes within 10 business days | BARDA | 1 | | |
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| 17. PRICE GROUP |
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| G. PREPARED BY (b) (6) Date 2021.05.20 14:04:07 -0400 | H. DATE | I. APPROVED BY (b) (6) Date 2021.05.20 14:04:07 -0400 | J. DATE |
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CONTRACT DATA REQUIREMENTS LIST
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Form Approved
OMB No. 0704-0188

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____ |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A005 | 2. TITLE OF DATA ITEM FDA Meeting Minutes | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DI-ADMN-81505 | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | | |
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| 16. REMARKS • Contractor shall notify BARDA of upcoming FDA meeting within 24 hours of scheduling Type A, B or C meetings OR within 24 hours of meeting occurrence for ad hoc meetings • Contractor shall forward FDA-issued preliminary comments and final minutes of any meeting with the FDA to BARDA within 2 calendar days of receipt | BARDA | 1 | | | |
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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

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CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____ |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A006 | 2. TITLE OF DATA ITEM Daily check in with project staff for COVID-19 Agreement | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DI-ADMN-81505 | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | b. COPIES | | |
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16. REMARKS

Upon request of the Government, the contractor shall participate in a daily check-in update if necessary with the Project Managers and additional project staff as needed (via teleconference or email). Potential triggers for the check-in include but are not limited to regulatory status changes, manufacturing and or/distribution problems that will affect delivery.

Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the Government, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.

- Preparation of materials will not be required but may be provided on an ad hoc basis as data or circumstances occur
- No agenda will be required for the meeting
- No meeting minutes are required
- Contractor will provide bulleted email updates following any call or in lieu of a call by 2PM for that day

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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

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| G. PREPARED BY (b) (6) Date 2021.05.20 14:05:09 -0400 | H. DATE | I. APPROVED BY (b) (6) Date 2021.05.20 14:05:09 -0400 | J. DATE |
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CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____ |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A007 | 2. TITLE OF DATA ITEM Monthly Progress Reports | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DI-MISC-80711A | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | b. COPIES | | |
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16. REMARKS
A consolidated submission of all slides and data presented at the biweekly telecons will serve as the monthly report. The report only consists of a summary of quantity of product delivered, when and location of the delivery.
• Monthly reports shall be submitted on or before the 20th day of the month covering the preceding month
Annual Reports submitted on the 30th calendar day of the month after each contract anniversary. Monthly progress reports are not required for the months when the Annual Report(s) are due, and Monthly/Annual Report(s) are not due during a month when the Final Report (final version, not draft) is due (see CDRL A009). The COR and CO will review the monthly reports with the Contractor and provide feedback
• Contractor shall provide FINAL versions of reports within 10 business days after receiving BARDA comments/edit

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| 17. PRICE GROUP |
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| 18. ESTIMATED TOTAL PRICE |
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CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved
OMB No. 0704-0188

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM <input type="checkbox"/> OTHER <input type="checkbox"/> |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A008 | 2. TITLE OF DATA ITEM Draft Technical Progress Report | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DI-MISC-80711A | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | b. COPIES | |
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| 16. REMARKS A draft Final Technical Progress Report containing a summation of the work performed over the entire Agreement. This report shall be in sufficient detail to fully describe the progress achieved under all milestones. Report should contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained during the Agreement. Descriptions and rationale for activities and milestones that were not completed as planned should be provided. The draft report shall be duly marked as 'Draft' • The Draft Technical Progress Report shall be submitted 75 calendar days before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP • AOR will provide feedback on draft report within 15 calendar days of receipt, which the Awardee shall consider incorporating into the Final Report | BARDA | 1 | | |
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| 17. PRICE GROUP |
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| G. PREPARED BY (b) (6) Date 2021.05.20 14:06:22 -0400 | H. DATE | I. APPROVED BY (b) (6) Date 2021.05.20 14:06:22 -0400 | J. DATE |
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CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved
OMB No. 0704-0188

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____ |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A009 | 2. TITLE OF DATA ITEM Final Technical Progress Report | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DI-MISC-80711 | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | b. COPIES | | |
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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

16. REMARKS
The Final Technical Progress Report incorporating feedback received from BARDA and containing a summation of the work performed for the entire agreement PoP. The final report shall document the results of the entire Agreement. The final report shall be duly marked as 'Final'. A cover letter with the report will contain a summary (not to exceed 200 words) of product delivery and distribution achieved during the performance of the Agreement

- The Final Technical report should be a comprehensive summary of the quantity of product delivered, when it was delivered and where

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| G. PREPARED BY [Redacted] <small>Date 2021.05.20 14:06:59 -04'00'</small> | H. DATE | I. APPROVED BY [Redacted] <small>Date 2021.05.20 14:06:59 -04'00'</small> | J. DATE |
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CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____ |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A010 | 2. TITLE OF DATA ITEM Product Development Source Material and Manufacturing Reports | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040 | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | b. COPIES | | |
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| 16. REMARKS The contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and location and nature of non-clinical and clinical study sites. The contractor will provide manufacturing reports and manufacturing dose tracking projections/actuals utilizing the "COVID-19 Dose Tracking Templates" or similar, on any contract/agreement that is manufacturing product, including product for clinical trial use. This deliverable only applies to material manufactured for this project, and for which the government has agreed to purchase. Awardee will submit Product Development Source Material Report o Within month of Agreement award o Within 30 days of substantive changes are made to sources and/or materials o Or on the 6th month contract anniversary. • Contractor will update the Dose Tracking Template weekly during manufacturing campaigns and daily during response operations (where a Public Health Emergency has been declared) and COVID-19 response, with the first deliverable submission within 15 days of award/modification. Updates to be provided weekly in advance of commercial-scale manufacturing and daily once material for use in response operations begins manufacture. • The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission • If corrective action is recommended, contractor must address all concerns raised by BARDA in writing • Product Development and Source Material report to be submitted via spreadsheet; Dose Tracking can be completed via spreadsheet or other format (e.g. XML or JSON) as agreed to by USG and company. | BARDA | 1 | | | |
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| 17. PRICE GROUP |
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| G. PREPARED BY (b) (6) Date 2021.05.20 14:07:31 -0400 | H. DATE | I. APPROVED BY (b) (6) Date 2021.05.20 14:07:31 -0400 | J. DATE |
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CONTRACT DATA REQUIREMENTS LIST
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Form Approved
OMB No. 0704-0188

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____ |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A011 | 2. TITLE OF DATA ITEM Contractor Locations | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DID 810003E | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | b. COPIES | |
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| 16. REMARKS The contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, an overall manufacturing point of contact, and work performed per location, to include sub-contractors. Contractor will submit Work Locations Report: <ul style="list-style-type: none"> • Within 5 business days of Agreement award • Within 30 business days after a substantive location or capabilities change • Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO Contractor format acceptable | BARDA | 1 | | |
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| 17. PRICE GROUP |
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| G. PREPARED BY (b) (6) Date 2021.05.20 14:08:19 -04'00' | H. DATE | I. APPROVED BY (b) (6) Date 2021.05.20 14:08:19 -04'00' | J. DATE |
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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____ |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A012 | 2. TITLE OF DATA ITEM Pandemic Management Plan | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040 | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | b. COPIES | |
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| 16. REMARKS A pandemic facility and/or operational management plan including change procedures from normal to pandemic operations contractor will prepare an operational plan to continue operations in the event of a declared pandemic emergency. Awardee will submit Pandemic Management Plan: • Draft within 15 days of award • Final within 30 days of award | BARDA | 1 | | |
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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____ |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A013 | 2. TITLE OF DATA ITEM Supply Chain and Distribution Tracking | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040 | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | b. COPIES |
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| 16. REMARKS Distribution Concept of Operations. BARDA, and MCM Manufacturers play an important role in the distribution of therapeutics to the American people under a nationwide response. BARDA will work with the manufacturer to monitor what is in the manufacturing pipeline using the enclosed dose tracking templates (see above). Awardee will relay final drug product information as it is being released to the BARDA/ASPR for allocation and ordering by state public health departments. This information will be returned to BARDA, the awardee and distributor. Distributors will use that information to ship therapeutics to sites of administration/end user. Provide the following information in order to coordinate the movement and delivery of antibody from manufacturing locations sites of administration/end user : • Provide a point of contact information (name, title, phone, email) for manufacturing / supply chain matters • Provide therapeutic labeling, packaging and distribution information as soon as it becomes available. At a minimum, include the following: • Primary Container Information• Number of doses per primary container• Unit of Sale (carton, box, package, other)• Quantity per Unit of Sale• National Drug Code (NDC) or NDC-like code under EUA• Unit of Sale dimensions (H,W, L)• Unit of Sale weight • Intermediate Package• Intermediate Package dimensions• Intermediate Package weight • Quantity Unit of Sale per pallet• Storage Requirements• Stability Information • Obtain concurrence on planned shipment protocols prior to transport • If therapeutic will require ultra-cold storage temperatures at the designated distribution centers, products should be packaged in 10-dose units to facilitate pick/pack process and reduce exposure of workers to ultra-cold temperatures. • Include the following DSCSA data elements, TI, TH and TS in packing lists. • Include the Agreement number on the packing list for all shipments • Include a copy of the MSDS (with QR code) in the packing list envelope with each shipment. • Send EDI 856 Advanced Shipment Notice for all products shipped to a USG directed location. Send electronic/scanned copies of all bulk shipment related documents to the AOR for three-way matching on the day shipment occurs. | BARDA | 1 | | | |
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| 17. PRICE GROUP |
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| 18. ESTIMATED TOTAL PRICE |
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(1 Data Item)

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____ |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A014 | 2. TITLE OF DATA ITEM Distribution Plan | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040 | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | | b. COPIES |
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16. REMARKS
This plan shall be developed in collaboration with the Government and will describe the process to distribute EUA-or BLA-approved product to point of care facilities, necessary to meet the Government's need for administration. The plan shall comply with applicable provisions of the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL113-54 (Nov 27, 2013), taking into account FDA's regular guidance for the COVID-19 public health response

Due 60 days after award unless otherwise agreed by the Parties

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| 17. PRICE GROUP |
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| G. PREPARED BY (b) (6) Date: 2021.05.20 14:09:58 -04'00' | H. DATE | I. APPROVED BY (b) (6) Date: 2021.05.20 14:09:58 -04'00' | J. DATE |
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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____ |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A015 | 2. TITLE OF DATA ITEM Distribution Memorandum of Understanding | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040 | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | b. COPIES | |
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16. REMARKS
This document is an understanding between ASPR, Merck, and the distributors to set forth the terms for each party to work together.

- Document will be delivered electronically within 60 days of award or as otherwise agreed by the parties

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| 15. TOTAL | 2 | 0 | 0 |

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| G. PREPARED BY (b) (6) Date: 2021.05.20 14:10:28 -0400 | H. DATE | I. APPROVED BY (b) (6) Date: 2021.05.20 14:10:28 -0400 | J. DATE |
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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 110 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="checked" type="checkbox"/> TM _____ OTHER _____ |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A017 | 2. TITLE OF DATA ITEM Quality Management Plan | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040 | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | b. COPIES |
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16. REMARKS
Plan may include, but is not limited to the manufacturing 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

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• Plan will be delivered electronically within 30 days of contract award to the CO and COR

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| G. PREPARED BY (b) (6) Date 2021.05.20 14:11:23 -0400' | H. DATE | I. APPROVED BY (b) (6) Date 2021.05.20 14:11:23 -0400' | J. DATE |
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CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____ |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A018 | 2. TITLE OF DATA ITEM Quality Agreement | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DID 810003E | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | b. COPIES | | |
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| <p>16. REMARKS</p> <p>Agreement will determine the conditions of acceptance by the USG of the purchased product. No product will be accepted by the USG until a quality agreement is in place. • Agreement will be signed by the USG and the manufacturer within 30 days of Agreement award</p> <p>• Agreement will be delivered electronically to the AO and AOR</p> <p>Contractor format acceptable</p> | BARDA | 1 | | |
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| | 15. TOTAL | | 2 | 0 |

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| G. PREPARED BY (b) (6) Date 2021.05.20 14:11:48 -0400 | H. DATE | I. APPROVED BY (b) (6) Date 2021.05.20 14:11:48 -0400 | J. DATE |
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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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A. CONTRACT LINE ITEM NO. 0001 **B. EXHIBIT** A **C. CATEGORY:**
TDP TM OTHER

D. SYSTEM/ITEM Therapeutics **E. CONTRACT/PR NO.** W911QY21C0031 **F. CONTRACTOR** Merck

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| 1. DATA ITEM NO. A019 | 2. TITLE OF DATA ITEM Release documentation for doses to be delivered | 3. SUBTITLE |
|---------------------------------|---|--------------------|

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| 4. AUTHORITY (Data Acquisition Document No.) DID 810003E | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | b. COPIES | | |
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| 16. REMARKS Contractor will deliver Certificate of Analysis and Certificate of Compliance for doses to be delivered. Documentation shall be provided at least 14 days prior to delivery Contractor format acceptable | BARDA | 1 | | | |
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| G. PREPARED BY (b) (6) Date: 2021.05.20 14:12:17 -0400 | H. DATE | I. APPROVED BY (b) (6) Date: 2021.05.20 14:12:17 -0400 | J. DATE |
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| 17. PRICE GROUP |
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CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved
OMB No. 0704-0188

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____ |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A020 | 2. TITLE OF DATA ITEM Security Plan | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DI-SESS-81921 | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | b. COPIES | | |
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| 17. PRICE GROUP |
| 18. ESTIMATED TOTAL PRICE |

16. REMARKS

Develop a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the obligations under this contract. This plan shall establish security practices and procedures that demonstrate how the Awardee will meet and adhere to the security program and shall be delivered to the Government within sixty (60) calendar days of award or as otherwise agreed by the parties. The Awardee shall also use commercially reasonable efforts to ensure all subawardees, consultants, researchers, etc. performing work on behalf of this effort, comply with all Government security requirements and Awardee security plans. The Awardee will flow-down the provisions of the Security Plan to (i) all sub-agreements/contracts executed after the Execution Date, and (ii) all sub-agreements/contracts executed prior to the Execution Date which cover manufacturing/fill/finish/storage activities under this Agreement; provided that in no event will the Awardee be required to flow-down any provisions to any sub-awardee which has a preexisting direct relationship with the Government. The Awardee will have a period of ninety (90) days to amend any existing agreements to reflect these flow-down requirements or, in the alternative, to demonstrate the sub-awardee's material compliance with any such flow-down requirements.

- The Government will review in detail and submit comments within ten (10) business days to the Agreements Officer (AO) to be forwarded to the Awardee. The Awardee shall review the Draft Security Plan comments, and, submit a Final Security Plan to the U.S. Government within thirty (30) calendar days after receipt of the comments.
- The Security Plan shall include a timeline for compliance of all the required security measures reasonably requested. Upon completion of initiating all security measures, the Awardee shall supply to the Agreements Officer a letter certifying compliance to the elements outlined in the Final Security Plan. by the Government.

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| 15. TOTAL | 2 | 0 | 0 |

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| G. PREPARED BY (b) (6) Date: 2021.05.20 14:12:45 -0400 | H. DATE | I. APPROVED BY (b) (6) Date: 2021.05.20 14:12:45 -0400 | J. DATE |
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CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____ |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A021 | 2. TITLE OF DATA ITEM Supply Chain Resiliency Plan | 3. SUBTITLE |
|---------------------------------|--|--------------------|

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| 4. AUTHORITY (Data Acquisition Document No.) DI-SESS-81921 | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | b. COPIES | |
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| 16. REMARKS A comprehensive Supply Chain Resiliency Program that provides identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods. A critical component is defined as any material that is essential to the product or the manufacturing process associated with that product. Included in the definition are consumables and disposables associated with manufacturing. NOT included in the definition are facility and capital equipment. Consideration of critical components includes the evaluation and potential impact of raw materials, excipients, active ingredients, substances, pieces, parts, software, firmware, labeling, assembly, testing, analytical and environmental componentry, reagents, or utility materials which are used in the manufacturing of a drug, cell banks, seed stocks, devices and key processing components and equipment. A clear example of a critical component is one where a sole supplier is utilized. The contractor shall identify key equipment suppliers, their locations, local resources, and the associated control processes at the time of award. This document shall address planning and scheduling for active pharmaceutical ingredients, upstream, downstream, component assembly, finished drug product and delivery events as necessary for the delivery of product. a) Communication for these requirements shall be updated as part of an annual review, or as necessary, as part of regular contractual communications. b) For upstream and downstream processing, both single-use and re-usable in-place processing equipment, and manufacturing disposables also shall be addressed. For finished goods, the inspection, labeling, packaging, and associated machinery shall be addressed taking into account capacity capabilities. c) The focus on the aspects of resiliency shall be on critical components and aspects of complying with the Agreement delivery schedule. Delivery methods shall be addressed, inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the contractually agreed deliveries. The Awardee shall articulate in the plan, the methodology for inventory control, production planning, scheduling processes and ordering mechanisms, as part of those agreed deliveries. a) Production rates and lead times shall be understood and communicated to the Agreements Officer or the Agreements Officer's Representative as necessary. b) Production throughput critical constraints should be well understood by activity and by design, and communicated to contractual personnel. As necessary, communication should be well understood by activity and by design, and communicated to contractual personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate. | BARDA | 1 | | | |
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| | 15. TOTAL | 2 | 0 | 0 | |

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| G. PREPARED BY (b) (6) | H. DATE | I. APPROVED BY (b) (6) | J. DATE |
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| 17. PRICE GROUP |
| 18. ESTIMATED TOTAL PRICE |

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM <input type="checkbox"/> OTHER _____ |
| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |

16. REMARKS (Continued)

Reports for critical items should include the following information:

- I. Critical Material
- II. Vendor
- III. Supplier, Manufacturing / Distribution Location
- IV. Supplier Lead Time
- V. Shelf Life
- VI. Transportation / Shipping restrictions

The AO and AOR reserve the right to request un-redacted copies of technical documents provided in response to this subsection, during the period of performance, for distribution within the Government.

Documents shall be provided within ten (10) days after AO issues the request. The contractor may arrange for additional time if deemed necessary, and agreed to by the AO. The Government will have Limited Rights in any documents provided under this subsection.

- Delivery of plan is within 60 calendar days of award

CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM <input type="checkbox"/> OTHER <input type="checkbox"/> |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A022 | 2. TITLE OF DATA ITEM Manufacturing Data Requirements | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DI-SESS-81921 | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | b. COPIES | | |
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| 16. REMARKS Detailed data regarding project materials, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing, processing, and fill/finish sites; and location and nature of non-clinical and clinical studies sites. <ul style="list-style-type: none"> The Government may provide a table in tabular format for Awardee to be used to submit such data, intended to ensure material development, which would include but not be limited to the following: <ol style="list-style-type: none"> Storage/inventory of ancillary materials (vials, needles, syringes, etc.) Shipment of ancillary materials (vials, needles, syringes, etc.) Disposal of ancillary materials (vials, needles, syringes, etc.) Seed development or other starting material manufacturing Bulk drug substance and/or adjuvant production Fill, finish, and release of product or adjuvant Storage/inventory of starting materials, bulk substance, or filled/final product or adjuvant Stability information of bulk substance and/or finished material Shipment of bulk substance of final material Disposal of bulk substance or final material Due within 30 calendar days of award | BARDA | 1 | | | |
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| | 15. TOTAL | 2 | 0 | 0 | 0 |

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| G. PREPARED BY (b) (6) Date: 2021.05.20 14:13:50 -0400 | H. DATE | I. APPROVED BY (b) (6) Date: 2021.05.20 14:13:50 -0400 | J. DATE |
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| 17. PRICE GROUP |
| 18. ESTIMATED TOTAL PRICE |

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved

OMB No. 0704-0188

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM <input type="checkbox"/> OTHER _____ |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A023 | 2. TITLE OF DATA ITEM BARDA Audit | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DI-SESS-81921 | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | Draft | b. COPIES |
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16. REMARKS

Contractor shall accommodate for cause site visits related to manufacturing of US supply by BARDA. If BARDA, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to BARDA

This deliverable only applies to material manufactured for this project, and for which the government has agreed to purchase.

- If issues are identified during the audit, Contractor shall submit a report to BARDA detailing the finding and corrective action(s) within 10 business days of the audit
- COR and CO will review the report and provide a response to the Contractor with 10 business days
- Once corrective action is completed, the Contractor will provide a final report to BARDA

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CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 110 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____ |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A024 | 2. TITLE OF DATA ITEM FDA Inspections | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DI-SESS-81921 | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | | b. COPIES |
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| 16. REMARKS In the event of an FDA inspection that occurs in relation to this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR) if available. Upon receipt of a 483 or EIR shared by a subcontractor, Contractor agrees to request authorization from the subcontractor to share the 483/EIR, redacted to the extent it concerns other products or proprietary information of the subcontractor unrelated to the contract or the manufacture of this product, with the KO and COR within 2 business days from that authorization but no later than 5 business days from Contractor receipt. The Contractor shall provide the COR and KO with copies of the plan for addressing areas of nonconformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. • Contractor shall notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice • Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 1 business day of receiving correspondence from the FDA or third party • Merck agrees to provide a copy of its response to the FDA in response to an audit report within 2 business days of submission to FDA. | BARDA | 1 | | | |
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| CONTRACT DATA REQUIREMENTS LIST <i>(1 Data Item)</i> | <i>Form Approved</i> <i>OMB No. 0704-0188</i> |
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The public reporting burden for this collection of information is estimated to average 110 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____ |
| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |

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| 1. DATA ITEM NO. A026 | 2. TITLE OF DATA ITEM Integrated Master Schedule (IMS) | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-81650 | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | b. COPIES | | |
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16. REMARKS

The contractor shall provide an IMS that illustrates project tasks, dependencies, durations throughout the period of performance, and milestones (GO/NO-GO). The IMS must map to the WBS, and provide baseline, and actual or forecast dates for completion of tasks

The IMS may be limited to those tasks associated with delivery of the product and other deliverables identified in the Statement of Work.

- The IMS is to be submitted in both PDF and Microsoft Project Form to the COR
- The first Draft of the IMS is due 30 business within contract award
- The Government will request revisions within 10 business days, at which point the schedule baseline for the period of performance will be set
- Thereafter an updated IMS is due concurrent with Monthly Technical Progress Reports
- During a public health emergency updates are due weekly, and any significant change (i.e. a change which would impact the schedule by greater than one week) must be reported immediately to the COR and/or designee.

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CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM <input type="checkbox"/> OTHER <input type="checkbox"/> |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A027 | 2. TITLE OF DATA ITEM Deviation Notification and Mitigation Strategy | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-81809 | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | |
| 8. APP CODE | | 11. AS OF DATE | 13. DATE OF SUBSEQUENT SUBMISSION see remarks | a. ADDRESSEE | b. COPIES |
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16. REMARKS
Process for changing IMS activities associated with cost and schedule as baselined. Contractor shall notify BARDA of significant proposed changes the IMS defined as schedule slippage of more than 30 days, which would require a PoP extension. Contractor shall provide a high level management strategy for risk mitigation
• Due at least 10 business days prior to the Contractor anticipating the need to implement changes

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CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved
OMB No. 0704-0188

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM <input type="checkbox"/> OTHER <input type="checkbox"/> |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A028 | 2. TITLE OF DATA ITEM Incident Report | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) contractor format acceptable | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION | | |
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| 16. REMARKS Contractor shall communicate to BARDA and document all critical programmatic concerns, issues, or probable risks that have or are likely to significantly impact project schedule. "Significant" is frequently defined as a 10% or greater schedule variance within a control account, but should be confirmed in consultation with the COR. Incidents that present liability to the project even without schedule impact, such as breach of GCP during a clinical study, must also be reported. • Due within 48 hours of activity or incident or within 24 hours for a security activity or incident • Email or telephone with written follow-up to COR and CO • Additional updates due to COR and CO within 48 hours of additional developments • Contractor shall submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues • If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by BARDA within 5 business days of receiving such concerns | BARDA | 1 | | | |
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CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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| A. CONTRACT LINE ITEM NO. 0001 | B. EXHIBIT A | C. CATEGORY: TDP _____ TM _____ OTHER <u>Regulatory documents</u> |
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| D. SYSTEM/ITEM Therapeutics | E. CONTRACT/PR NO. W911QY21C0031 | F. CONTRACTOR Merck |
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| 1. DATA ITEM NO. A029 | 2. TITLE OF DATA ITEM FDA Correspondence and Submissions | 3. SUBTITLE |
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| 4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040 | 5. CONTRACT REFERENCE SOW | 6. REQUIRING OFFICE BARDA |
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| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | 12. DATE OF FIRST SUBMISSION see remarks | 14. DISTRIBUTION |
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16. REMARKS
All material regulatory documentation submitted to the FDA and received from the FDA, including EUA applications, NDAs, label updates, supplemental NDAs, annual reports, safety reports (e.g., DSURs/PAERS), FDA information requests, responses to FDA information requests, and protocol submissions/amendments, shall be submitted to BARDA no later than 2 calendar days of the submission or receipt of the communication.

| a. ADDRESSEE | b. COPIES | | |
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CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
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| A. CONTRACT LINE ITEM NO. 0001 | | B. EXHIBIT A | | C. CATEGORY: TDP <input checked="" type="checkbox"/> TM <input type="checkbox"/> OTHER <input type="checkbox"/> | | | | |
| D. SYSTEM/ITEM Therapeutics | | | E. CONTRACT/PR NO. W911QY21C0031 | | F. CONTRACTOR Merck | | | |
| 1. DATA ITEM NO. A032 | 2. TITLE OF DATA ITEM Educational Materials | | | 3. SUBTITLE | | | | |
| 4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-81809 | | | 5. CONTRACT REFERENCE SOW | | 6. REQUIRING OFFICE BARDA | | | |
| 7. DD 250 REQ | 9. DIST STATEMENT REQUIRED | 10. FREQUENCY see remarks | | 12. DATE OF FIRST SUBMISSION see remarks | | 14. DISTRIBUTION | | |
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| 16. REMARKS Contractor will develop learning material to assist in administration and increase appropriate uptake of their drug to the public including but not limited to pamphlets, infomercials, websites, etc., subject to FDA guidance, regulation, and/or review. • Drafts of initial materials will be submitted to BARDA for review prior to EUA. Final versions of these materials are due at least 7 days prior to EUA. Any subsequent materials will be due to BARDA for review at least 7 days prior to finalization. | | | | | BARDA | 1 | | |
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W911QY-21-C-0031
Attachment 0001
Security Requirements

Date: 26 October 2020
of pages: 6

Security Requirements

Access and General Protection/Security Policy and Procedures

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

Operational Security (OPSEC)

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

Security Plan

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

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

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

Security Requirements:

1. Facility Security Plan

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

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

2. Site Security Master Plan

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

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| | <ul style="list-style-type: none"> i) to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access. j) Must have a written manual key accountability and inventory process. k) Physical access controls should present a layered approach to critical assets within the facility. |
| Employee/Visitor Identification | <ul style="list-style-type: none"> a) Should issue company photo identification to all employees. b) Photo identification should be displayed above the waist anytime the employee is on company property. c) Visitors should be sponsored by an employee and must present government issued photo identification to enter the property. d) Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises at all times. |
| Security Fencing | Requirements for security fencing will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment. |
| Protective Security Forces | Requirements for security officers will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment. |
| Protective Security Forces Operations | <ul style="list-style-type: none"> a) Must have in-service training program. b) Must have Use of Force Continuum. c) Must have communication systems available (i.e., landline on post, cell phones, handheld radio, and desktop computer). d) Must have Standing Post Orders. e) Must wear distinct uniform identifying them as security officers. |
| 5. Security Operations | |
| Description: | |
| Information Sharing | <ul style="list-style-type: none"> a) Establish formal liaison with law enforcement. b) Meet in person at a minimum annually. Document meeting notes and keep them on file for a, minimum of 12 months. POC information for LE Officer that attended the meeting must be documented. c) Implement procedures for receiving and disseminating threat information. |
| Training | <ul style="list-style-type: none"> a) Conduct new employee security awareness training. b) Conduct and maintain records of annual security awareness training. |
| Security Management | <ul style="list-style-type: none"> a) Designate a knowledgeable security professional to manage the security of the facility. b) Ensure subcontractor compliance with all Government security requirements. |
| 6. Personnel Security | |
| Description: | |
| Records Checks | Verification of social security number, date of birth, citizenship, education credentials, five-year previous employment history, five-year previous residence history, FDA disbarment, sex offender registry, credit check based upon position within the company; motor vehicle records check as appropriate; and local/national criminal history search. |
| Hiring and Retention Standards | <ul style="list-style-type: none"> a) Detailed policies and procedures concerning hiring and retention of employees, employee conduct, and off boarding procedures. b) Off Boarding procedures should be accomplished within 24 hour of employee leaving the company. This includes termination of all network access. |
| 7. Information Security | |
| Description: | |

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

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