

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1 CONTRACT ID CODE	PAGE OF PAGES 1 30
2 AMENDMENT/MODIFICATION NO P00004	3 EFFECTIVE DATE 11-Feb-2021	4 REQUISITION/PURCHASE REQ NO SEE SCHEDULE	5 PROJECT NO (If applicable)	
6 ISSUED BY W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	CODE W911QY	7 ADMINISTERED BY (If other than item 6) DEFENSE CONTRACT MANAGEMENT AGENCY DCMA BOSTON 495 SUMMER STREET BOSTON MA 02210-2138		CODE S2206A
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) MODERNA US, NC. (b) (6) 200 TECHNOLOGY SQ CAMBRIDGE MA 02139-3578			9A. AMENDMENT OF SOLICITATION NO.	
			9B. DATED (SEE ITEM 11)	
			X 10A. MOD. OF CONTRACT/ORDER NO. W911QY20C0100	
			X 10B. DATED (SEE ITEM 13) 09-Aug-2020	
CODE 8PTMD	FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS				
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.				
12. ACCOUNTING AND APPROPRIATION DATA (If required) See Schedule				
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.				
A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.				
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).				
X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: See Block 14 Continuation Page				
D. OTHER (Specify type of modification and authority)				
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input checked="" type="checkbox"/> is required to sign this document and return <u>1</u> copies to the issuing office.				
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Modification Control Number: (b) (6) 211178 See Block 14 Continuation Page				
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect				
15A. NAME AND TITLE OF SIGNER (Type or print) (b) (6)			16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) (b) (6) Contracting Officer	
			TEL: (b) (6) EMAIL: (b) (6)	
15B. CONTRACTOR/OFFEROR (b) (6)		15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY (b) (6)	
(Signature of person authorized to sign)			(Signature of Contracting Officer)	
			16C. DATE SIGNED 11Feb2021	

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

OBLIGATION AMOUNT: (b) (4)

a. The purpose of this modification (P00004) is to:

- Exercise, fund Option 2 CLINs 2001AA, 2001AB, 2001AC for a total of (b) (4) (Authority FAR 52.217-7)
- Add clauses H.16 & H.17, and revise the delivery schedule for the Base period, Option 1, and Option 2 IAW the table contained within H.16 (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)
- Revise the table in Section G back to previous amounts, due to an administrative error on modification no. P00003, where the amounts were revised (Authority FAR 52.232-16)
- Update Contract Data Requirement List (CDRL) no.'s A003, A008, A009, A011, A014, A021, and the corresponding information to the CDRLs in Section C, Statement of Work. (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)

b. This modification was requested by the program office to meet the Government's mission requirements.

c. The total contract value and total funded amount has increased by (b) (4) from (b) (4) to (b) (4).

All other terms and conditions remain unchanged. Please see below for details.

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by (b) (4) from (b) (4) to (b) (4).

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0001

The CLIN extended description has changed from:

The contractor shall produce and deliver (b) (4) of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP), IAW Section C, Statement of Work (SOW) and CDRLs (Exhibit A) on this contract.

To:

The contractor shall produce and deliver (b) (4) of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP) IAW clause H.16 Delivery Schedule, Section C Statement of Work (SOW), and CDRLs (Exhibit A) on this contract.

CLIN 1001

The CLIN extended description has changed from:

The contractor shall produce and deliver (b) (4) of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP), IAW Section C, Statement of Work (SOW) and CDRLs (Exhibit A) on this contract.

To:

The contractor shall produce and deliver (b) (4) of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP) IAW clause H.16 Delivery Schedule, Section C Statement of Work (SOW), and CDRLs (Exhibit A) on this contract.

CLIN 2001

The CLIN extended description has changed from:

The contractor shall produce and deliver (b) (4) of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP), IAW Section C, Statement of Work (SOW) and CDRLs (Exhibit A) on this contract.

To:

The contractor shall produce and deliver (b) (4) of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP) IAW clause H.16 Delivery Schedule, Section C Statement of Work (SOW), and CDRLs (Exhibit A) on this contract.

The option status has changed from Option to Option Exercised.

SUBCLIN 2001AA

The option status has changed from Option to Option Exercised.

SUBCLIN 2001AB

The option status has changed from Option to Option Exercised.

SUBCLIN 2001AC

The option status has changed from Option to Option Exercised.

SECTION C - DESCRIPTIONS AND SPECIFICATIONS

The following have been modified:

STATEMENT OF WORK LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE

C.1 **SCOPE.** The Department of Defense and Health and Human Services (HHS) require large scale manufacturing of vaccine doses in support of the national emergency response to the Coronavirus Disease 2019 (COVID-19) for the United States Government (USG) and the US population.

C.1.1 **Background.** In December 2019, a novel coronavirus now known as SARS-CoV-2 was first detected in Wuhan, Hubei Province, People's Republic of China, causing outbreaks of the coronavirus disease COVID-19 that has now spread globally. The Secretary of Health and Human Service declared a public health emergency on January 31, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19. On March 1, 2020, the President of the United States, pursuant to sections 01 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.) and consistent with section 1135 of the Social Security Act (SSA), as amended (42 U.S.C. 1320b-5), proclaimed that the COVID-19 outbreak in the United States constitutes a national emergency.

C.1.1.1 Under Operation Warp Speed (OWS), the Department of Defense and HHS are leading a whole of nation effort to ensure development of promising vaccine, diagnostic and therapeutic candidates and ensure that these medical countermeasures are available in the quantities required to reduce SARS-CoV-2 transmission, identify prior and/or current infection, and improve patient care, thereby mitigating the impact of COVID-19 on the nation and its people. The DoD Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRD) is providing expertise and contracting support to HHS, in compliance with PL 115-92 Authorization Letter for DoD Medical Priorities, through an Interagency Agreement, signed April 23, 2020. As OWS products progress to clinical trials to evaluate the safety and efficacy of vaccines and therapeutics, it is critical that, in parallel, the USG supports large scale manufacturing so that vaccine doses or therapeutic treatment courses are immediately available for nationwide access as soon as a positive efficacy signal is obtained and the medical countermeasures are authorized for widespread use.

C.1.2 **Objective:** The objective of this effort is to obtain the following:

- a. Base Period: Large scale manufacturing of 100 million vaccine doses
- b. Option Period 1: Large scale manufacturing of 100 million vaccine doses
- c. Option Period 2: Large scale manufacturing of 100 million vaccine doses
- d. Option Period 3: Large scale manufacturing of 100 million vaccine doses
- e. Option Period 4: Large scale manufacturing of 100 million vaccine doses

The Base Period is 9 months, with overlapping options for a total of 20 months if all options are exercised.

C.2 **APPLICABLE DOCUMENTS.**

C.2.1 Federal Documents:

C.2.1.1 Title 21 Code of Federal Regulations (CFR), Food and Drugs: Part 210, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General; and, Part 211, Current Good Manufacturing Practice In Manufacturing, Processing, Packing, or Holding of Drugs; General.

(https://www.ecfr.gov/cgi-bin/text-idx?SID=a95cab20f443897a400bb7e44a27cf4c&mc=true&tpl=/ecfrbrowse/Title21/21cfrv4_02.tpl#0)

C.3 **REQUIREMENTS.** Independently, and not as an agent of the USG, in accordance with the Proposal submitted by Moderna US, Inc. in response to Solicitation Number W911QY20R0043, Titled, "Advanced

Procurement of mRNA-1273 Vaccine for Prevention of SARS-CoV-2 Coronavirus (COVID-19)”, dated July 10, 2020 (and any subsequent USG-approved revisions thereto), the contractor shall provide all necessary services, qualified personnel, material, equipment and facilities (not otherwise provided by the USG under the terms of this contract) to perform the specific tasks set forth below.

C.3.1 Contract Line Item Number (CLIN) 0001 - Base Period: Large Scale Manufacturing of 100 Million Vaccine Doses.

C.3.1.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million Final Drug Product (FDP) doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include, the following tasks and other activities reasonably contemplated by such task:

C.3.1.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.1.1.2 cGMP manufacturing of 100 million doses fully compliant with 21 CFR 210 and 211.

C.3.1.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated as appropriate.

C.3.1.1.4 Coordinating with FDA to establish an approved commercial vial label, carton and packaging insert (printed or electronic).

C.3.1.1.5 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements, subject to any exceptions established by or the enforcement discretion of the FDA, including “Exemption from Certain Product Tracing and Product Identification Requirements Under Section 582 of the FD&C Act” (April 2020).

C.3.1.1.6 In coordination with the USG, the contractor shall conduct a demonstration of the vaccine shipping process prior to the first delivery of FDP doses at a time mutually agreed to by the contractor and the USG. Moderna shall provide specifications and details associated with the shipping process and containers (IAW CDRL A005) to enable the USG to adequately plan and prepare for potential distribution of the vaccine.

C.3.1.1.7 Following release of product the contractor shall, promptly deliver product to the designated delivery site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. In the unforeseen event that a designated delivery site cannot receive product and the contractor provides storage beyond 20 days of product release, the contract will be subject to modification for acceptance purposes.

C.3.1.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.1.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.1.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and Contracting Officer’s Representative (COR) within (b) (4) of a scheduled FDA audit or within (b) (4) of an ad hoc site visit or audit if the FDA does not provide advance notice. The 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 (b) (4) of

receiving correspondence from the FDA or third party in accordance with CDRL A002. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [REDACTED] of submittal of the audit report in accordance with CDRL A002.

C.3.1.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.2 **CLIN 1001 - Option Period 1: Large Scale Manufacturing of 100 Million Vaccine Doses.**

C.3.2.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.2.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.2.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.2.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.

C.3.2.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.2.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.2.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.2.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.2.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within (b) (4) of a scheduled FDA audit or within (b) (4) of an ad hoc site visit or audit if the FDA does not provide advance notice. The 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 (b) (4) of receiving correspondence from the FDA or third party in accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within (b) (4) of submittal of the audit report in accordance with CDRL A002.

C.3.2.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.3 CLIN 2001 - Option Period 2: Large Scale Manufacturing of 100 Million Vaccine Doses.

C.3.3.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.3.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.3.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.3.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated as appropriate.

C.3.3.1.4 Ensuring that the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.3.1.5 Following release the contractor shall deliver product to the nearest designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.3.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.3.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.3.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within (b) (4) of a scheduled FDA audit or within (b) (4) of an ad hoc site visit or audit if the FDA does not provide advance notice. The 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 (b) (4) of receiving correspondence from the FDA or third party in accordance with CDRL A002. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within (b) (4) of submittal of the audit report in accordance with CDRL A002.

C.3.3.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.4 CLIN 3001 - Option Period 3: Large Scale Manufacturing of 100 Million Vaccine Doses.

C.3.4.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.4.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.4.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.4.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.

C.3.4.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.4.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.4.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.4.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.4.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within (b) (4) of a scheduled FDA audit or within (b) (4) of an ad hoc site visit or audit if the FDA does not provide advance notice. The 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 (b) (4) of receiving correspondence from the FDA or third party in accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within (b) (4) of submittal of the audit report in accordance with CDRL A002.

C.3.4.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding mRNA-1273 for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.5 CLIN 4001 - Option Period 4: Large Scale Manufacturing of 100 Million Vaccine Doses.

C.3.5.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.5.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.5.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.5.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.

C.3.5.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.5.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.5.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.5.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.5.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within (b) (4) of a scheduled FDA audit or within (b) (4) of an ad hoc site visit or audit if the FDA does not provide advance notice. The 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 (b) (4) of receiving correspondence from the FDA or third party in accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within (b) (4) of submittal of the audit report in accordance with CDRL A002.

C.3.5.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.4 **CLIN 0002: Data Deliverables.** The contractor shall provide the following in accordance with the Contract Data Requirements List (CDRL), DD Forms 1423, provided at Appendix A.

C.4.1 Monthly Inventory Report (CDRL A003), detailing at a minimum, raw materials, Bulk mRNA, formulated LNPs, and the fill, finish, and released product.

C.4.2 Quality Management Plan. The contractor shall provide a Quality Management Plan, in accordance with CDRL A004, describing the quality policy and objectives, management review, competencies and training, process document control, feedback, evaluation, corrective action and preventive action, process improvement, measurement, and data analysis processes. The framework is normally divided into infrastructure, senior

management responsibility, resource management, lifecycle management, and quality management system evaluation.

C.4.3 Shipping Documentation (CDRL A005) for all Finished Drug Product (FDP) transferring from the contractor's fill/finish facility to a USG facility. The contractor shall obtain concurrence on planned shipment protocols prior to transport.

C.4.4 Expiring Items Report (CDRL A006) for all FDP in the USG's possession.

C.4.5 Key Personnel Listing (CDRL A007).

C.4.6 Monthly Technical Progress Report (CDRL A008), to include an Integrated Master Schedule, identifying key activities and contract status.

C.4.7 Final Technical Report (CDRL A009), documenting the work performed and results obtained for the entire contract period of performance.

C.4.8 Supply Chain Resiliency Plan (SCRCP). The contractor shall provide, in accordance with CDRL A010 and CDRL Attachment 0001, a comprehensive SCRCP that provides for identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods, and key equipment suppliers and their locations, including addresses, points of contact, and work performed per location, to include subcontractors.

C.4.9 Risk Management Plan (RMP). The Contractor shall provide an RMP in accordance with CDRL A011 that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy shall capture how the corrective action will reduce impacts on cost, schedule and performance. **The following RMP information shall be included in the Monthly Technical Progress Report (CDRL A008).**

Risk Register content:

- a. **Manuf/FF -risks or possible delays. If none N/A**
- b. **Supply chain – same as above**
- c. **Distribution challenges – same as above**
- d. **Regulatory – same as above**

C.4.10 Manufacturing Reports and Dose Tracking. The Contractor shall provide, in accordance with CDRL A013, manufacturing reports and manufacturing dose tracking projections and actuals utilizing the USG-provided "COVID-19 Dose Tracking Template" (CDRL Attachment 0003).

C.4.11 Product Acceptance Report (for each lot of Drug Product). The contractor shall provide, in accordance with CDRL A014, pictures of the drug product with lot number, drug product lot tree, list of associated deviations (from drug substance and product), and a Certificate of Analysis.

C.4.12 Incident Report. The contractor shall communicate to BARDA and document all critical programmatic concerns, issues, or probable risks that have or are likely to significantly impact project schedule and/or cost and/or performance in accordance with CDRL A016. "Significant" is frequently defined as a 10% or greater cost or schedule variance within a control account, but should be confirmed in consultation with the COR. Incidents that present liability to the project even without cost/schedule impact, such as breach of GCP during a clinical study, shall also be reported.

C.4.13 FDA Correspondence. The contractor shall provide any correspondence between Contractor and FDA relevant to the scope of this contract and submit in accordance with CDRL A017.

C.4.14 **Press Releases.** The contractor shall accurately and factually represent the work conducted under this contract in all press releases. The contractor shall provide an advance copy of any press release in accordance with CDRL A018.

C.4.15 **Manufacturing Development Plan.** The contractor shall provide a Manufacturing Development Plan, in accordance with CDRL A025, describing 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).

C.5 **Administration.**

C.5.1 **Post Award Teleconference.** The contractor shall host a Post Award Teleconference within 15 calendar days after contract award.

C.5.1.1 The contractor shall provide an Agenda, IAW CDRL A020, detailing the planned activities for the subsequent 30 calendar days and shall discuss agenda items for the Post Award Kickoff Meeting.

C.5.1.2 The contractor shall provide Meeting Minutes IAW CDRL A021.

C.5.2 **Post Award Kickoff Meeting.** The contracting officer may request the contractor host a contract Kick-Off Meeting within 30 calendar days after contract award via teleconference. The contracting officer shall establish the date and time of the conference and prepare the agenda to include discussion on contract activities and schedule.

C.5.3 **Bi-Weekly Teleconference.** The contractor shall participate in bi-weekly teleconferences (or more frequent meetings required by the USG if warranted based on contract activities) to discuss performance on the contract.

C.5.4 The contractor shall provide an Agenda, IAW CDRL A020; Meeting Minutes in accordance with CDRL A021; and, Presentation Material in accordance with CDRL A022 for each of the aforementioned teleconferences or meetings throughout the contract period of performance.

C.5.5 **Daily "Check-In".** The contractor shall participate in a daily "check-in" (via teleconference or email) to address key cost, schedule and technical updates. Daily updates may be shared with senior USG leaders during the COVID- 19 response and should be provided on a non-confidential basis, unless the update includes confidential information in which case, the contractor shall provide the update in both confidential and non-confidential formats. Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the USG, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.

C.6 **Security.**

C.6.1 **Access and General Protection/Security Policy and Procedures.** The contractor shall provide all information required for background checks necessary to access critical information related to OWS, and to meet USG installation access requirements to be accomplished by the installation Director of Emergency Services or Security Office. The contractor employees shall comply with all personnel identity verification requirements as directed by the USG and/or local policy. In addition to the changes otherwise authorized by the changes clause of this contract, should the security status of OWS change the USG may require changes in the contractor's security matters or processes. In addition to the industry standards for employment background checks, the contractor shall be willing to have key individuals, in exceptionally sensitive positions, identified for additional vetting by the United States USG.

C.6.2 **Security Program and Plan.** The contractor shall implement a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the USG's requirement. The contractor's security practices and procedures shall be detailed in a Security Plan, in accordance with CDRL A019, and shall demonstrate how the contractor shall meet and adhere to the security requirements outlined in CDRL Attachment 0002. This plan shall be delivered to the USG within 45 days of award, and the USG 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 Security Plan comments, and, submit a final Security Plan to the U.S. USG 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 outlined in CDRL Attachment 0002.

C.6.3 Operational Security (OPSEC). The contractor shall develop and submit an OPSEC Standard Operating Procedure (SOP)/Plan IAW CDRL A024. The contractor shall identify in the SOP/Plan 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.

C.7 CLIN 0002 Vendor Managed Inventory (VMI). The Contractor shall provide the capability to store the vaccine for up to 52 weeks, up to 100M doses of mRNA-1273 vaccine, in accordance with product labeling. The contractor shall, in accordance with paragraph C.3.1.1.6, ensure the product storage of FDP doses for up to 12 months prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Risk of loss of or damage to supplies shall remain with the contractor until delivery of Filled Drug Product (FDP) to a government facility. The contractor shall store the product to insure product quality with audible alarms and contacting. The contractor shall notify the USG within (b) (4) of detection of an incident with the potential to impact product quality, and implement corrective actions to mitigate the incident. . BARDA/JPEO-CBRND personnel may conduct Quality Audits of the storage facility, when deemed necessary. The contractor shall notify the USG of Corrective/Preventive actions within (b) (4) of detection of an incident with potential to impacts product quality. BARDA/JPEO-CBRND personnel may conduct Quality Audits of the storage facility, when deemed necessary.

C.7.1 The USG will provide the contractor advance notice of the required delivery locations for the vaccine. The contractor shall ship mRNA-1273 vaccines to designated locations (b) (4) in the United States. The contractor shall be responsible for shipment of all vaccine product whether acceptance is conducted at origin or destination. Regardless of where acceptance occurs, risk of loss of or damage to supplies shall remain with the contractor until delivery of Filled Drug Product (FDP) to a government facility.

C.7.2 The vaccine product shall be shipped and tracked by the distribution vendor's shipping tracking number, to the USG-designated sites within the continental United States.

C.7.3 The contractor shall retain physical risk of loss for all product stored as VMI until subsequent delivery to and acceptance by the USG at the USG-designated site. Implementation of a Vendor Managed Inventory Plan/SOP (CDRL A012) shall be provided to the USG. If the drug product is initially delivered to a USG site instead of VMI, risk of loss will transfer upon delivery and acceptance at the USG-designated site. Notwithstanding either of the foregoing sentences, the contractor shall not be liable for loss of or damage to supplies caused by the negligence of officers, agents, or employees of the USG acting within the scope of their employment.

SECTION E - INSPECTION AND ACCEPTANCE

The following have been modified:

E1. Inspection:

Vaccine CLINs:

Quality inspection of Filled Drug Product (FDP) shall occur when the Contractor performs release testing to confirm that products complies with Contractor's release specifications and criteria. Contractor will submit the Certificate of Analysis for quality inspection of all drug product lots in BARDA Data Infrastructure (BDI) system. Initial

Inspection under this contract will be performed at the Contractor's facility, or the subcontractor facility, by the BARDA Contracting Officer Technical Representative (COTR).

The Government shall inspect each shipment of product delivered to it hereunder for visible damage and quantity (b) (4). In the event Contractor supplies any product to the Government and it is established that such Product was damaged or does not include the required quantities at the time of final delivery, the Government shall promptly notify Contractor in writing (b) (4). A BDI extract of the inspection documentation shall also be submitted in Wide Area Workflow (WAWF) as supporting documentation for invoice submittals.

Storage CLIN:

In the event the USG requires storage of the FDP to a Vendor Managed Inventory (VMI) location, quantity inspection shall be conducted by submission of shipping or other documentation into WAWF confirming quantity to VMI location. Physical inspection of the FDP shall be conducted upon receipt of product to USG CDC location.

Data CLIN:

Inspection of all reports and Contract Data Requirement List (CDRL) under this contract will be performed at Destination by duly authorized representative of the Government.

E.2 Acceptance

a. Acceptance at origin shall occur at the contractor or subcontractor facility. Acceptance at destination shall occur at a government designated CDC location. Regardless of where acceptance occurs, the contractor is responsible for final delivery of Filled Drug Product (FDP) to a government designated CDC location.

b. Acceptance of vaccines under this agreement will be performed by the COTR in the BDI system, which constitutes government acceptance at origin. Documentation of acceptance shall be submitted in accordance with WAWF instructions.

c. Acceptance of storage services under VMI CLIN No. 0002 shall occur upon satisfactory physical and quantity inspection of FDP upon delivery at USG designated CDC location. Acceptance of Data CLIN No. 0004 shall occur in WAWF by the KO.

d. The parties acknowledge that acceptance may depend on the compliance with the Contractor's product specifications. The KO and COR may prior to acceptance consult with FDA under its authority under Public Law 115-92 to determine whether the material to be delivered meets the Contractor's product specifications. To this end, Contractor agrees to provide a letter to FDA authorizing the Government to engage in dialog with FDA about the ultimate compliance of this product with the Contractor's product specifications prior to acceptance. BARDA/COR will accept product according to the approved Product Acceptance Procedure.

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule item for SUBCLIN 1001AB has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
---------------	----------	-----------------	------------------

(b) (4)

(b) (4)

(b) (1) (B)
(b) (6)
(b) (1) (B)
(b) (6)

W56XNH

FOB: Destination

To:

DELIVERY DATE

QUANTITY

SHIP TO ADDRESS

DODAAC /
CAGE

(b) (4)

(b) (4)

(b) (1) (B)
(b) (6)
(b) (1) (B)
(b) (6)

W56XNH

FOB: Destination

The following Delivery Schedule item for SUBCLIN 1001AC has been changed from:

DELIVERY DATE

QUANTITY

SHIP TO ADDRESS

DODAAC /
CAGE

(b) (4)

(b) (4)

(b) (1) (B)
(b) (6)
(b) (1) (B)
(b) (6)

W56XNH

FOB: Destination

To:

DELIVERY DATE

QUANTITY

SHIP TO ADDRESS

DODAAC /
CAGE

(b) (4)

(b) (4)

(b) (1) (B)
(b) (6)
(b) (1) (B)
(b) (6)

W56XNH

FOB: Destination

The following Delivery Schedule item for SUBCLIN 2001AA has been changed from:

DELIVERY DATE

QUANTITY

SHIP TO ADDRESS

DODAAC /
CAGE

(b) (4)	(b) (4)	(b) (1) (B) (b) (6) (b) (1) (B)	W56XNH
		(b) (6)	
		FOB: Destination	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
(b) (4)	(b) (4)	(b) (1) (B) (b) (6) (b) (1) (B)	W56XNH
		(b) (6)	
		FOB: Destination	

The following Delivery Schedule item for SUBCLIN 2001AB has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
(b) (4)	(b) (4)	(b) (1) (B) (b) (6) (b) (1) (B)	W56XNH
		(b) (6)	
		FOB: Destination	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
(b) (4)	(b) (4)	(b) (1) (B) (b) (6) (b) (1) (B)	W56XNH
		(b) (6)	
		FOB: Destination	

The following Delivery Schedule item for SUBCLIN 2001AC has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
(b) (4)	(b) (4)	(b) (1) (B) (b) (6) (b) (1) (B) (b) (6) FOB: Destination	W56XNH

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
(b) (4)	(b) (4)	(b) (1) (B) (b) (6) (b) (1) (B) (b) (6) FOB: Destination	W56XNH

The following have been modified:

F.1 The contractor shall ship mRNA-1273 vaccines to the designated locations listed below. The contractor shall be responsible for secure shipment of all vaccine product whether acceptance is conducted at origin or destination.

Delivery Locations:

(b) (1) (B)

(b) (6)

(b) (1) (B)

(b) (6)

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 2001AA:

AF: 0212021202220400000665654255 S.0074658.5.44 6100.9000021001 A5XAH (CIN GFEB001160755900001) was increased by (b) (4) from (b) (4) to (b) (4)

The contract ACRN AF has been added.

The CIN GFEB001160755900001 has been added.

The Cost Code (b) (4) has been added.

SUBCLIN 2001AB:

AG: 0212021202220400000665654255 S.0074658.5.44.2 6100.9000021001 A5XAH (CIN GFEB001160755900002) was increased by (b) (4) from (b) (4) to (b) (4)

The contract ACRN AG has been added.

The CIN GFEB001160755900002 has been added.

The Cost Code (b) (4) has been added.

SUBCLIN 2001AC:

AH: 0212021202220400000665654255 S.0074658.5.44.3 6100.9000021001 A5XAH (CIN GFEB001160755900003) was increased by (b) (4) 0 from (b) (4) to (b) (4)

The contract ACRN AH has been added.

The CIN GFEB001160755900003 has been added.

The Cost Code (b) (4) has been added.

The following have been modified:

G.1 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.

Procuring Contracting Officer:

(b) (6)

Bldg. 1, General Greene Avenue
Natick, MA 01760-5011

Contract Specialist:

(b) (6)

Bldg. 1, General Greene Avenue
Natick, MA 01760-5011

G.2 GOVERNMENT TECHNICAL POINT OF CONTACT

(b) (6)

Biologist/Project Officer
200 C Street, SW
Washington, DC 20201

G.3 CONTRACTOR'S CONTRACT ADMINISTRATION

(b) (6)

Moderna US, Inc.
200 Technology SQ.
Cambridge, MA 02139-3578

G.4 PLACES OF PERFORMANCE

Moderna US, Inc.
200 Technology SQ.
Cambridge, MA 02139-3578

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/ACO or office of the PCO/ACO 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.

G.6 PERFORMANCE BASED PAYMENT

Performance-based payments (PBP) are authorized under this contract in accordance with FAR 52.232-32. The contractor shall bill for the PBP upon achievement of the completion criteria identified in Attachment 0007, Performance-based Payment Milestone Table. Upon achievement of the completion criteria, the contractor shall bill for the PBP for the base and each option IAW the following schedule:

(b) (4)

(b) (4)

Delivery Invoicing: PBPs are a type of contract financing and are recouped by the Government through deductions of payments otherwise due to the contractor for the partial or complete delivery of contract items. The deductions are made by applying a liquidation rate to the price of delivered contract items. Attachment 0008, Performance-based Payment Milestone Billing Plan, identifies the contractor invoicing schedule for liquidation. The contractor shall submit all invoices IAW Attachment 0008 dated 4 December 2020.

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

(ii) For fixed price line items—

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

Invoice and receiving report document type

(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	HQ0337
Issue By DoDAAC	W911QY
Admin DoDAAC	S2206A
Inspect By DoDAAC	W56XNH
Acceptor	W911QY
Ship To	TDB

(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) / DCMA Boston-AFAW, Administrative Contracting Officer (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_ htm/current/PGI204_71.htm#payment_instructions

SECTION H - SPECIAL CONTRACT REQUIREMENTS

The following have been modified:

H.1 Key Personnel

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

Name	Title
(b) (6)	

H.2 Substitution of Key Personnel

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

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

H.3 Disclosure of Information:

Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO 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 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 operations of the activity, 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 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.4 Publication and Publicity

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

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

(b) Unless authorized in writing by the CO, the contractor shall not display 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-20-C-0100."

H.5 Confidentiality of Information

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

ALL REQUIREMENTS OF THIS SECTION H.5 MUST BE PASSED TO ALL SUB-CONTRACTOR.

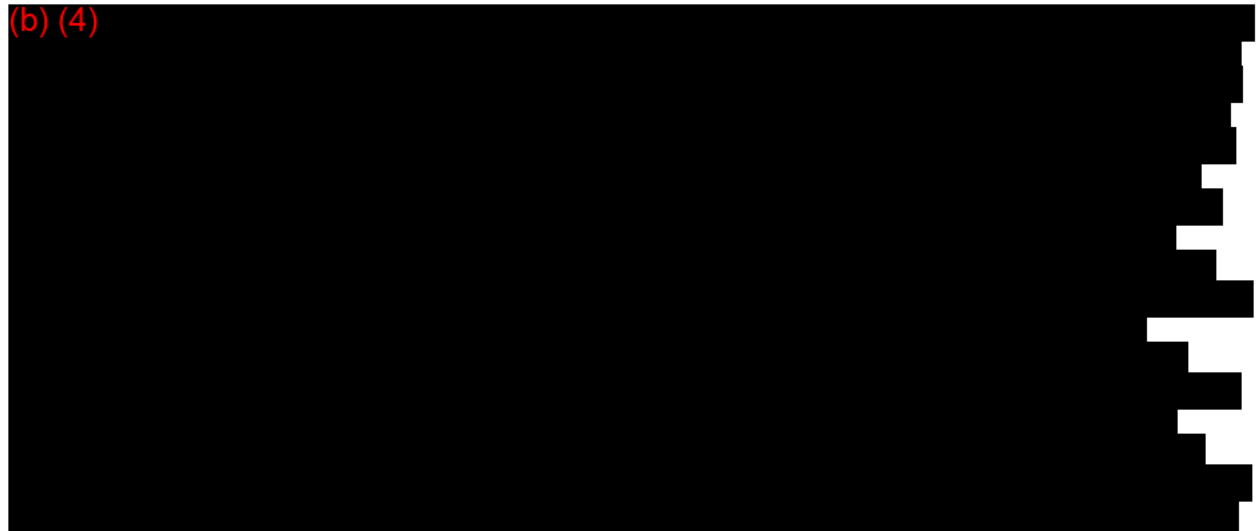
H.6 Regulatory Rights

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 mRNA-1273, Moderna vaccine for SARS-CoV-2 Coronavirus (the "Technology"). The Contractor is the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), emergency use authorization (EUA), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) 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 (b) (4) of award.

(b) (4)



H.7 Performance Based Payment Liquidated under Termination

Performance Based Payments (PBPs) have been authorized as a method of financing under this contract. In the event the Moderna's mRNA-1273 COVID Vaccine is unsuccessful in its bid to obtain EUA or FDA approval, the Government may issue a Termination for Convenience (T4C) in whole or in part, on this contract. Upon notice of a T4C, the contractor shall submit a termination settlement proposal, IAW FAR 52.249-2, Termination for Convenience of the Government (Fixed-Price).

H.8 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 Moderna 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) [Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

(b) (4) [Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

(b) (4) [Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

(b) (4) [Redacted]

[Redacted]

contractor continues to work, the contractor shall not be entitled to an equitable adjustment by the government.

H.12 Transportation to Final Destination

During the course of performance under this contract, the Government may require storage of the filled drug product (FDP) before delivery to the final government 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 vaccine to its final destination as identified on this contract. Regardless of where acceptance occurs, risk of loss of or damage to supplies shall remain with the contractor until delivery of FDP to a government facility.

H.13 Validation of IP/Data

The Parties acknowledge that background intellectual property and technical data assertions have been made and evaluated by the parties. The parties agree that, should additional information relevant to these assertions become available, the parties will reevaluate said assertions as necessary in the future.

(b) (4) [Redacted]

[Redacted]

H.15 Base & Option 1 Delivery Acceleration

In an effort to accelerate production of the mRNA-1273 vaccine, the Government agrees to fund eight additional drug product manufacturing slots (including fill, pack and label) within the Base Period and ten drug product manufacturing slots within the Option 1 period via a Modification to the contract. If these manufacturing slots are

successfully utilized, there will be up to 18 drug manufacturing slots funded above what was projected by Moderna and assumed within the price per dose for the doses of mRNA-1273 vaccine delivered in the Base Period and Option 1. However, because the Government is funding the additional slots within the Base and Option 1 periods in order to accelerate production, the Government is entitled to an adjustment under the conditions outlined. The Government and Moderna agree to the following:

1. If the Government exercises Option 2 (NLT 15 May):

a. Moderna will reduce the cost of Option 2 by \$1,051,000 for each successfully accelerated drug product fill under the Base Period (limited to the eight additional slots) and \$819,000 for each successfully accelerated drug product fill under Option 1 (limited to the ten additional slots).

2. If the Government does not exercise Option 2 (NLT 15 May):

a. In the event Moderna timely cancels the manufacturing slots and/or is able to otherwise fully utilize the slots originally reserved for production in the Option 2 period, Moderna agrees to credit the Government \$1,051,000 for each of the eight slots and \$819,000 for each of the ten slots that Moderna utilizes. In no case shall the number of drug product manufacturing slots credited exceed the number of successfully accelerated drug product manufacturing fills under the Base Period and Option 1. It is understood that Moderna will make all good-faith efforts to fill reserved slots or cancel reservations in a timely manner (i.e. within the time period required by the subcontractor).

b. In the event that Moderna is unable to fill those reserved slots (i.e. due to lack of demand) and cancels slots, Moderna shall be entitled to recoup those reservation cancellation costs from the USG. The process is outlined as follows:

1.) Moderna shall submit documentation to the USG of the following:

- i.) Cancellation notice to the subcontractor,
- ii.) The basis of the cancellation. and
- iii.) Cancellation fees incurred.

2.) Moderna shall reduce credits to the USG under paragraph 2a) of this clause, IAW agreed cancellation costs incurred.

3.) Bi-lateral agreement of the final credit shall be included in a modification to the contract. Net credit shall be deducted from final payments under the contract.

H.16 Delivery Schedule, as revised 11Feb2021 via modification P00004

(b) (4)



(b) (4)

(b) (4)

H.17 Post-Termination Disposition of Undelivered Product

For the avoidance of doubt, if the USG elects to terminate the exercised CLINs prior to acceptance and delivery in full of the required quantities of mRNA-1273, Moderna will be free to direct any unaccepted/undelivered supplies of mRNA-1273 to customers other than the USG, at its discretion, without further obligation of either party with regard to such unaccepted/undelivered supplies of mRNA-1273. The contract will be bilaterally modified to decrease the quantities by the agreed upon volume.

SECTION I - CONTRACT CLAUSES

The following have been modified:

252.232-7007 LIMITATION OF GOVERNMENT'S OBLIGATION (APR 2014)

(a) Contract line item (b) (4) is incrementally funded. For this item, the sum of (b) (4) of the total price is presently available for payment and allotted to this contract. An allotment schedule is set forth in paragraph (j) of this clause.

(b) For item(s) identified in paragraph (a) of this clause, the Contractor agrees to perform up to the point at which the total amount payable by the Government, including reimbursement in the event of termination of those item(s) for the Government's convenience, approximates the total amount currently allotted to the contract. The Contractor is not authorized to continue work on those item(s) beyond that point. The Government will not be obligated in any event to reimburse the Contractor in excess of the amount allotted to the contract for those item(s) regardless of anything to the contrary in the clause entitled "TERMINATION FOR THE CONVENIENCE OF THE GOVERNMENT." As used in this clause, the total amount payable by the Government in the event of termination of applicable contract line item(s) for convenience includes costs, profit and estimated termination settlement costs for those item(s).

(c) Notwithstanding the dates specified in the allotment schedule in paragraph (j) of this clause, the Contractor will notify the Contracting Officer in writing at least ninety days prior to the date when, in the Contractor's best judgment, the work will reach the point at which the total amount payable by the Government, including any cost for termination for convenience, will approximate 85 percent of the total amount then allotted to the contract for performance of the applicable item(s). The notification will state (1) the estimated date when that point will be reached and (2) an estimate of additional funding, if any, needed to continue performance of applicable line items up to the next scheduled date

for allotment of funds identified in paragraph (j) of this clause, or to a mutually agreed upon substitute date. The notification will also advise the Contracting Officer of the estimated amount of additional funds that will be required for the timely performance of the item(s) funded pursuant to this clause, for subsequent period as may be specified in the allotment schedule in paragraph (j) of this clause, or otherwise agreed to by the parties. If after such notification additional funds are not allotted by the date identified in the Contractor's notification, or by an agreed substitute date, the Contracting Officer will terminate any item(s) for which additional funds have not been allotted, pursuant to the clause of this contract entitled "TERMINATION FOR THE CONVENIENCE OF THE GOVERNMENT".

(d) When additional funds are allotted for continued performance of the contract line item(s) identified in paragraph (a) of this clause, the parties will agree as to the period of contract performance which will be covered by the funds. The provisions of paragraph (b) through (d) of this clause will apply in like manner to the additional allotted funds and agreed substitute date, and the contract will be modified accordingly.

(e) If, solely by reason of failure of the Government to allot additional funds, by the dates indicated below, in amounts sufficient for timely performance of the contract line item(s) identified in paragraph (a) of this clause, the Contractor incurs additional costs or is delayed in the performance of the work under this contract and if additional funds are allotted, an equitable adjustment will be made in the price or prices (including appropriate target, billing, and ceiling prices where applicable) of the item(s), or in the time of delivery, or both. Failure to agree to any such equitable adjustment hereunder will be a dispute concerning a question of fact within the meaning of the clause entitled "disputes."

(f) The Government may at any time prior to termination allot additional funds for the performance of the contract line item(s) identified in paragraph (a) of this clause.

(g) The termination provisions of this clause do not limit the rights of the Government under the clause entitled "DEFAULT." The provisions of this clause are limited to work and allotment of funds for the contract line item(s) set forth in paragraph (a) of this clause. This clause no longer applies once the contract is fully funded except with regard to the rights or obligations of the parties concerning equitable adjustments negotiated under paragraphs (d) or (e) of this clause.

(h) Nothing in this clause affects the right of the Government to this contract pursuant to the clause of this contract entitled "TERMINATION FOR CONVENIENCE OF THE GOVERNMENT."

(i) Nothing in this clause shall be construed as authorization of voluntary services whose acceptance is otherwise prohibited under 31 U.S.C. 1342.

(j) The parties contemplate that the Government will allot funds to this contract in accordance with the following schedule:

(b) (4)

(b) (4)

(End of clause)

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

Document Type	Description	Page #	Date
Exhibit A	CDRLs	15	11 Feb 2021
Attachment 0001	Supply Chain Resiliency Plan for CDRL A010	3	23 July 2020
Attachment 0002	(b) (1) (B) [REDACTED]	7	23 July 2020
Attachment 0003	(b) (4) [REDACTED]	Excel	15 July 2020
Attachment 0004	Data Rights	3	7 August 2020
Attachment 0005	(b) (4) [REDACTED]	2	7 August 2020
Attachment 0006	ModernaTx, Inc. Background Intellectual Property	3	6 August 2020
Attachment 0007	Performance Base Payment Milestone Schedule	2	7 August 2020
Attachment 0008	Performance Base Payment Milestone Billing Plan	17	4 December 2020
Attachment 0009	HRPAS Moderna Letter	1	3 September 2020

(End of Summary of Changes)

Supply Chain Resiliency Plan for CDRL A010

Attachment 0001

As of 23 July 2020

**ATTACHMENT 0001
TO
CONTRACT DATA REQUIREMENTS
LIST A010**

Supply Chain Resiliency Plan

The contractor shall provide a comprehensive Supply Chain Resiliency Plan that provides for identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods.

1. 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.

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

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

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

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

4. Reports for critical items should include the following information:

- a) Critical Material
- b) Primary vendor and secondary vendor, if applicable
- c) Supplier, Manufacturing / Distribution Location
- d) Supplier Lead Time
- e) Shelf Life
- f) Transportation / Shipping restrictions

- g) Comparability studies, if applicable
- h) Amount of material (dose equivalent) in inventory

Security Plan

Attachment 0002

As of 23 July 2020


ATTACHMENT 0002

**CONTRACT DATA REQUIREMENTS
LIST A019**

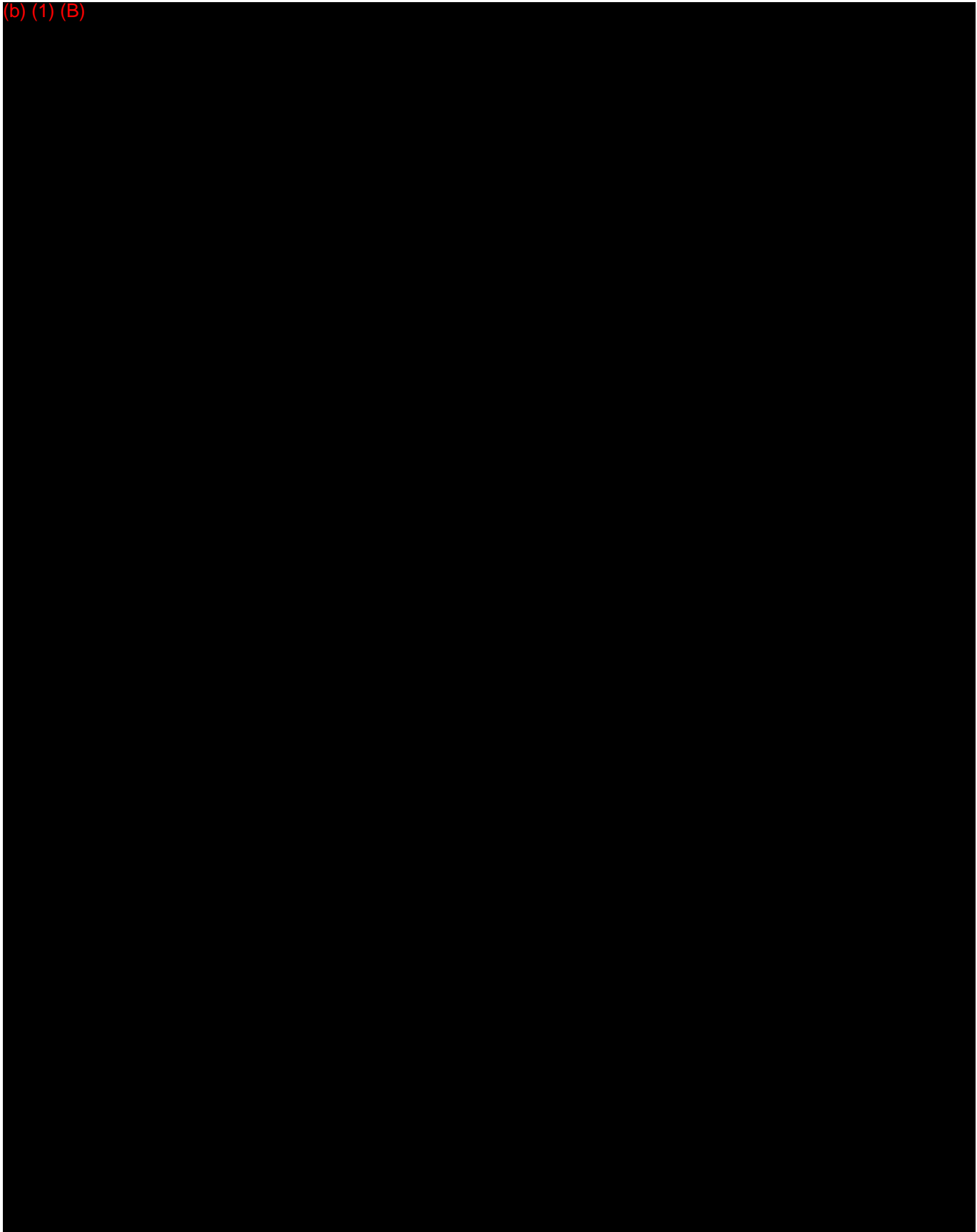
BARDA SECURITY REQUIREMENTS

The contractor shall provide a Security Plan which shall address the following:

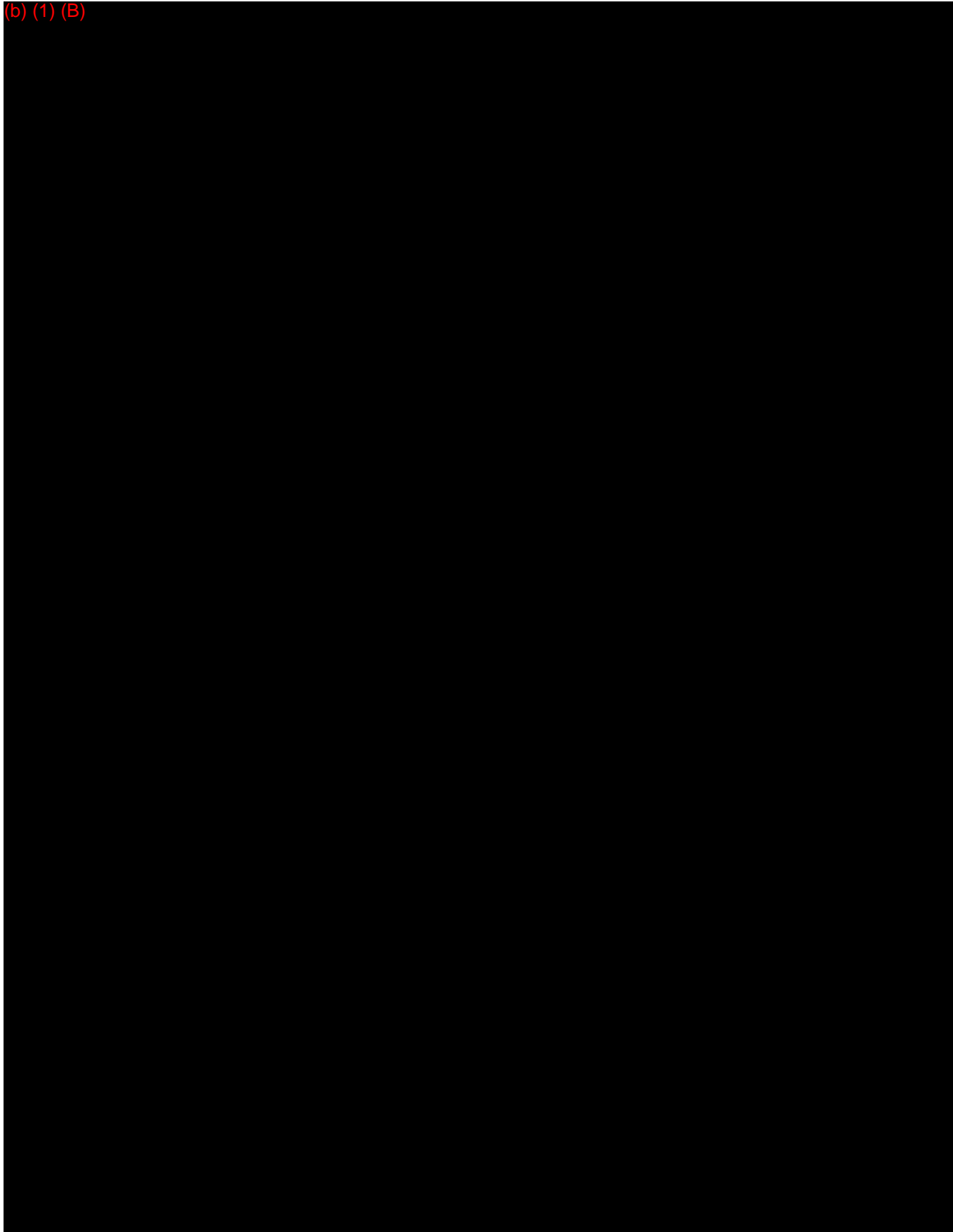
(b) (1) (B)



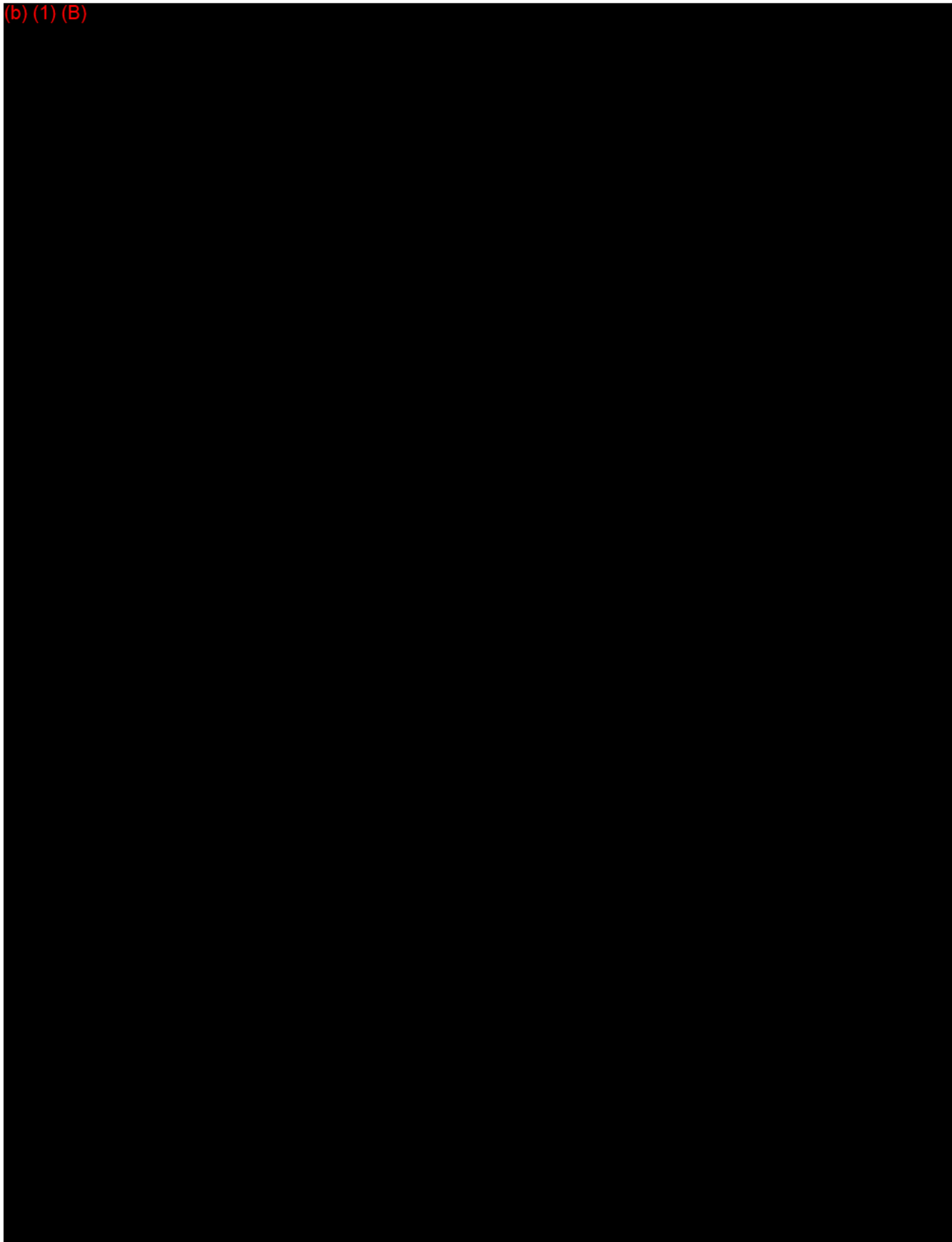
(b) (1) (B)



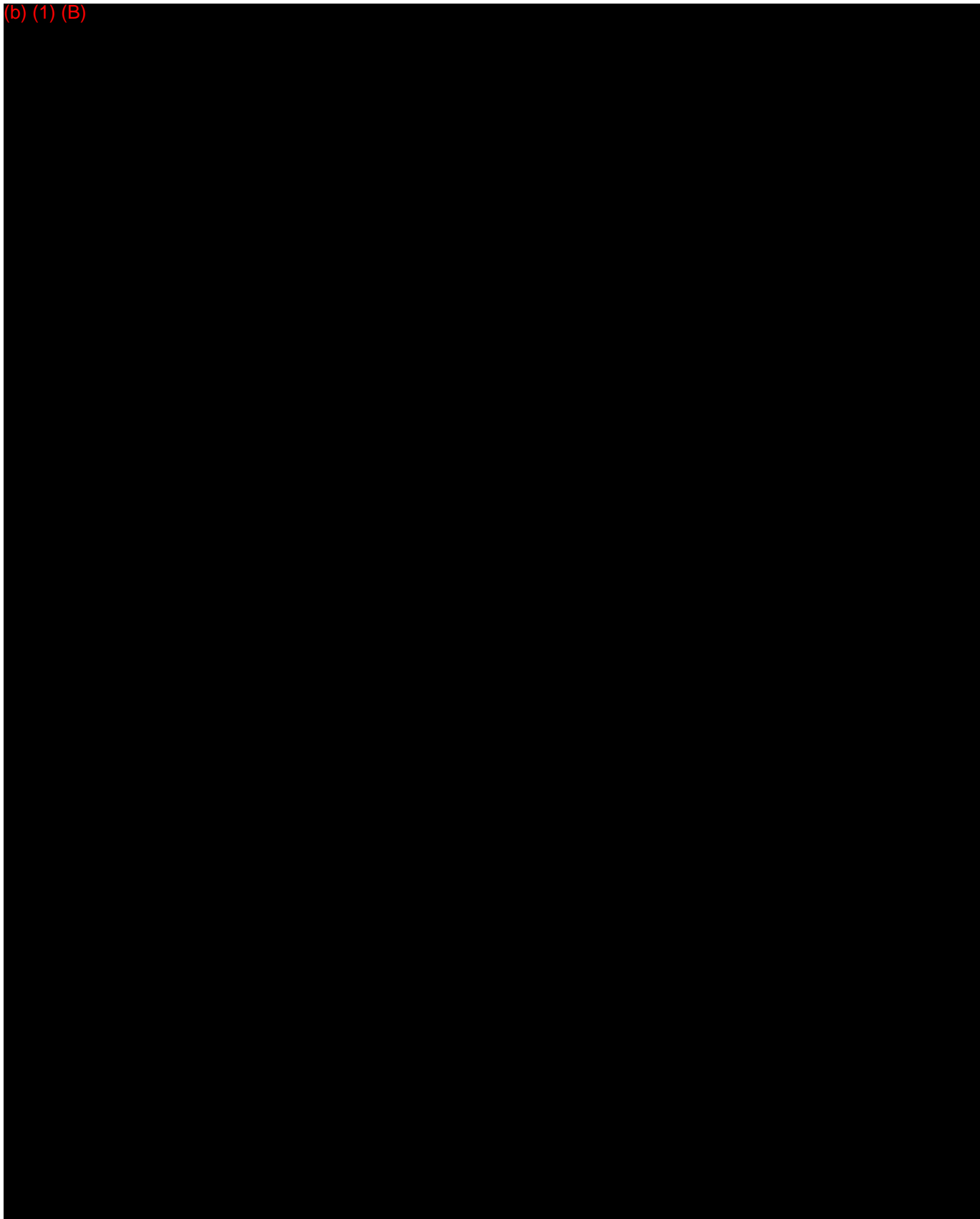
(b) (1) (B)



(b) (1) (B)



(b) (1) (B)



(b) (1) (B)



Data Rights

Attachment 0004

As of 7 August 2020

Data Rights Restrictions

Limited Rights Data

The following are Moderna's technical data assertions required by DFAR 252.227-7017 ("Identification and assertion of use, release, or disclosure restrictions"). Notwithstanding any contrary representation by the Contractor on the System for Award Management or any contrary provision in the contract, the following categories of information developed exclusively at private expense will, if provided to the Government, be considered limited rights data subject to the restrictions specified in DFAR 227.7013. These restrictions apply to any component of information covered by this provision, regardless of whether a component is included in a contract deliverable. The Government will, as applicable, retain government purpose rights or unlimited rights in technical data generated in performance or included in a deliverable as required by DFARS 252.227-7013 or another applicable data rights clause to the extent that any component of such technical data (i) was developed in whole or in part with Government funds, (ii) pertains to an item developed in whole in part with Government funds, or (iii) was first produced in performance of a Government contract subject to FAR 52.227-14. Nothing in this Contract or this Attachment affects any data rights that the Government may already have under prior agreements between Moderna and the Government, including with respect to Agreement Nos. (b) (4)

The Government will not reverse engineer or otherwise evaluate materials provided under this Contract to reproduce the type of information described below without Moderna's prior written consent.

(b) (4)



(b) (4)



August 7, 2020

W911QY-20-C-0100
Data Rights
Attachment 0004
Page 3 of 3

(b) (4)

Attachment 0005

As of 7 August 2020

W911QY-20-C-0100

(b) (4)

(b) (4)



August 7, 2020

W911QY-20-C-0100

(b) (4)

Attachment 0005

Page 2 of 2

Moderna Tx, Inc. Background Intellectual Property

Attachment 0006

As of 6 August 2020

Description of Moderna, Inc. Representative Intellectual Property

(b) (4)



Description of Moderna, Inc. Representative Intellectual Property

(b) (4)



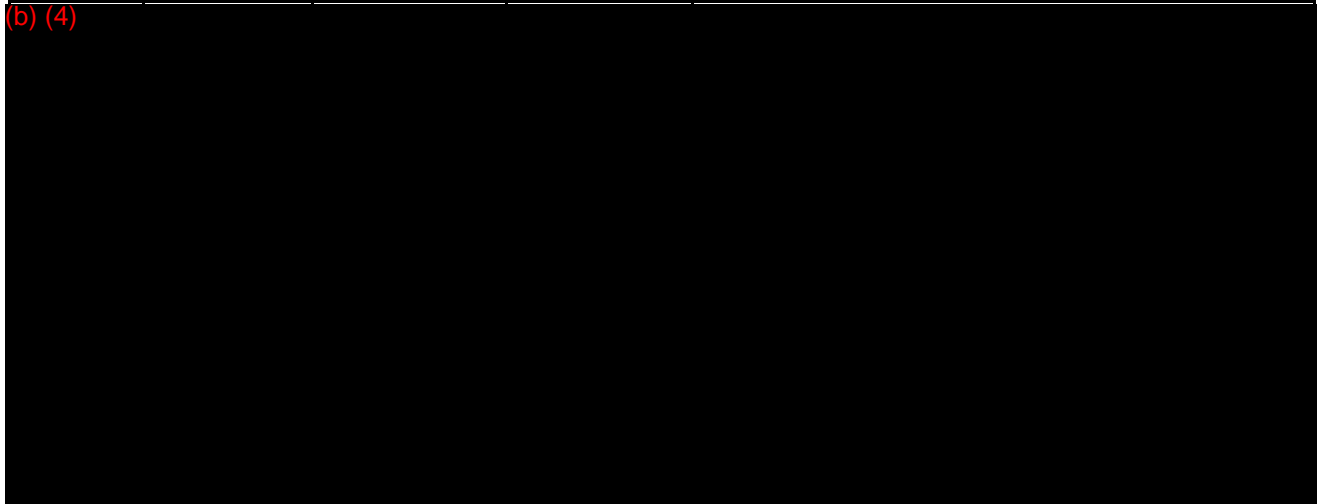
Performance Based Payment (PBP) Milestone Schedule

Attachment 0007

As of 7 August

CLIN	Milestone	Severable/ Cumulative	Price	Milestone Completion Verification Method
001				Moderna shall provide: 1) written confirmation from the CMO network that sufficient capacity has been reserved; and, 2) written confirmation of reservation of sufficient raw materials along with a manufacturing schedule.
	Capacity and Raw Material Reservation	Severable	\$601,400,000	

(b) (4)



Performance Base Payment (PBP) Milestone Billing Plan

Attachment 0008

As of 4 December 2020



DEPARTMENT OF DEFENSE
OPERATION WARP SPEED TASK FORCE
200 INDEPENDENCE AVENUE
WASHINGTON, DC 20201


OWS-COO

03 September 20

MEMORANDUM FOR Vaccine Contractor Moderna

SUBJECT: Health Resources Priorities and Allocations System (HRPAS) Rating for Department of Defense Contract W911QY20C0100

1. Department of Defense Contract #W911QY20C0100 has been rated under the Health Resources Priorities and Allocations System (HRPAS) regulation (45 C.F.R. part 101) supporting Operation Warp Speed (OWS). The purpose of this rating is to promote national defense by ensuring this contract, as well as its subcontracts, are prioritized over other orders. This means orders, including meeting delivery dates, under this contract, and supporting contracts are legally required to take precedent over other unrated orders for the same product.
2. Acceptance and rejection of rated orders (101.33). Mandatory acceptance is required unless the delivery date is at issue. If unable to meet that date, inform the Contracting Officer (CO) of the earliest date on which delivery can be made and offer to accept the order on the basis of that date. Scheduling conflicts with previously accepted lower rated or unrated orders are not sufficient reason for rejection under this section. Do not accept a DO rated order for delivery on a date which would interfere with delivery of any previously accepted DO or DX rated orders. However, you are required to notify the CO of the earliest delivery date otherwise possible. See 101.33 for justifications for Optional rejection. This is a rated order placed for the purpose of emergency response and notice of acceptance or rejection of this HRPAS priority rating is required by the CO within 48 hours.
3. You are required to place rated orders with your suppliers/subcontractors for items necessary to fulfill the requirements under this contract. You must inform suppliers/subcontractors that your orders will be prioritized over other unrated orders.
4. Supplies acquired pursuant to this rating may ONLY be used to fulfill the requirements of this contract and cannot be used for other efforts. Use of supplies acquired under the order for any other purpose will be considered a breach of the terms of this contract and subject your company to adverse contract action and remedy. In addition, violations of the provisions of the Defense Production Act may subject the offender to civil and criminal penalties, to include fines up to \$10,000, imprisonment for up to one year, or both.
5. Please contact your contracting officer if you have any questions on information in this letter.


GUSTAVE F. PERNA
General, USA
Chief Operating Officer

Contract Data Requirements List (CDRL)

Exhibit A

As of 11 February 2021

CONTRACT DATA REQUIREMENTS LIST
(2 Data Items)

Form Approved
OMB No. 0704-0188

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

A. CONTRACT LINE ITEM NO. 0002	B. EXHIBIT A	C. CATEGORY: TDP _____ TM _____ OTHER <u>General/Admin Data</u>
--	------------------------	---

D. SYSTEM/ITEM LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE	E. CONTRACT/PR NO. W911QY-20-C-0100	F. CONTRACTOR ModernaUS, Inc.
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1. DATA ITEM NO. A001	2. TITLE OF DATA ITEM Quality Audit Finding and Response Record (QAFRR)	3. SUBTITLE BARDA Audit Findings Report
---------------------------------	---	---

4. AUTHORITY (Data Acquisition Document No.) DI-SESS-81923	5. CONTRACT REFERENCE C.3.1.2.1, C.3.2.2.1, C.3.3.2.1	6. REQUIRING OFFICE ASPR BARDA
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7. DD 250 REQ NA	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION			
8. APP CODE A		11. AS OF DATE 0	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES		
					Draft	Final	
						Reg	Repro

16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . The contractor shall detail the findings and corrective action(s). 8. The US Government (USG) will respond with comments or approval within 10 calendar days after receipt. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit within 10 business days of an Audit. 13. The contractor shall incorporate USG comments and provide a final report to the USG upon completion of corrective action. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: (b) (6) and the Contracting Officer** (KO), (b) (6) LT: Letter of Transmittal (via email).	15. TOTAL	1	2	0
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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

1. DATA ITEM NO. A002	2. TITLE OF DATA ITEM Research and Development of Medical Products Regulated by the U.S. Food & Drug Administration	3. SUBTITLE FDA Interactions and Inspections Documentation
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4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040 (Tailored)	5. CONTRACT REFERENCE C.3.1.2.2, C.3.2.2.2, C.3.3.2.2	6. REQUIRING OFFICE ASPR BARDA
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7. DD 250 REQ NA	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION			
8. APP CODE A		11. AS OF DATE 0	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES		
					Draft	Final	
						Reg	Repro

16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . Pages 7-8, Paragraphs 2.b.(1) through (5) apply. 8. The US Government (USG) will respond with comments or approval within 10 calendar days after receipt. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit FDA Audit Report (including subcontractors) within 1 business day of receiving correspondence from the FDA or third party. Provide FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation within 3 business days of FDA interaction, unless otherwise specified by the USG. 13. Within 10 business days of audit report, the contractor shall provide a plan for addressing areas of nonconformance, if any are identified, and submit within 30 days the report provided to the FDA. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: (b) (6) and the Contracting Officer** (KO), (b) (6) LT: Letter of Transmittal (via email).	15. TOTAL	2	2	0
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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

G. PREPARED BY (b) (6)	H. DATE 2/5/2021	I. APPROVED BY (b) (6)	J. DATE 2/5/2021
----------------------------------	----------------------------	----------------------------------	----------------------------

CONTRACT DATA REQUIREMENTS LIST
(2 Data Items)

Form Approved
OMB No. 0704-0188

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

A. CONTRACT LINE ITEM NO. 0002	B. EXHIBIT A	C. CATEGORY: TDP _____ TM _____ OTHER <u>General/Admin Data</u>
--	------------------------	---

D. SYSTEM/ITEM LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE	E. CONTRACT/PR NO. W911QY-20-C-0100	F. CONTRACTOR ModernaUS, Inc.
---	---	---

1. DATA ITEM NO. A003	2. TITLE OF DATA ITEM Contractor Furnished Material (CFM) Report	3. SUBTITLE Monthly Inventory Report
---------------------------------	--	--

4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-82049	5. CONTRACT REFERENCE C.4.1	6. REQUIRING OFFICE ASPR BARDA
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7. DD 250 REQ NO NO	9. DIST STATEMENT REQUIRED C	10. FREQUENCY MTHLY	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION		
8. APP CODE NA		11. AS OF DATE NA	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES	
					Draft	Final
					Reg	Repro

16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. & 13. Submit concurrent with monthly Technical Progress Report (CDRL A008). 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: (b) (6) and the Contracting Officer** (KO), (b) (6) LT: Letter of Transmittal (via email).	15. TOTAL →
	1 1 0

1. DATA ITEM NO. A004	2. TITLE OF DATA ITEM Research and Development of Medical Products Regulated by the U.S. Food & Drug Administration	3. SUBTITLE Quality Management Plan
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4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040 (Tailored)	5. CONTRACT REFERENCE C.4.18	6. REQUIRING OFFICE ASPR BARDA
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7. DD 250 REQ NO NA	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION		
8. APP CODE A		11. AS OF DATE 0	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES	
					Draft	Final
					Reg	Repro

16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . Page 10, paragraph f.(2) applies. 8. The US Government (USG) will respond with comments or approval within 10 calendar days after receipt. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit within 30 calendar days after contract award. 13. The contractor shall incorporate USG comments and resubmit within 10 calendar days after receipt. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: (b) (6) and the Contracting Officer** (KO), (b) (6) LT: Letter of Transmittal (via email).	15. TOTAL ▶
	1 1 0

G. PREPARED BY (b) (6)	H. DATE 2/5/2021	I. APPROVED BY (b) (6)	J. DATE 2/5/2021
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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST
(2 Data Items)

Form Approved
OMB No. 0704-0188

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

A. CONTRACT LINE ITEM NO. 0002	B. EXHIBIT A	C. CATEGORY: TDP _____ TM _____ OTHER <u>General/Admin Data</u>
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D. SYSTEM/ITEM LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE	E. CONTRACT/PR NO. W911QY-20-C-0100	F. CONTRACTOR ModernaUS, Inc.
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1. DATA ITEM NO. A006	2. TITLE OF DATA ITEM Task Directive Documentation	3. SUBTITLE Expiring Items Report
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4. AUTHORITY (Data Acquisition Document No.) DI-SESS-82206 (Tailored)	5. CONTRACT REFERENCE C.4.3	6. REQUIRING OFFICE ASPR BARDA
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7. DD 250 REQ NA	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION		
8. APP CODE NO		11. AS OF DATE NA	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES	
					Draft	Final

16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . Only paragraph cc applies. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. & 13. Submit 30 calendar days prior to product expiration throughout contract period of performance. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: (b) (6) and the Contracting Officer** (KO), (b) (6) LT: Letter of Transmittal (via email).	ASPR BARDA* CCAP-SCN**	0 0	1 LT	0 0
15. TOTAL → 0 1 0				

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

1. DATA ITEM NO. A007	2. TITLE OF DATA ITEM Contractor's Personnel Roster	3. SUBTITLE Key Personnel Listing
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4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-81834A	5. CONTRACT REFERENCE C.4.5	6. REQUIRING OFFICE ASPR BARDA
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7. DD 250 REQ NA	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION		
8. APP CODE A		11. AS OF DATE 0	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES	
					Draft	Final

16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . 8. The US Government (USG) will respond with comments or approval within 10 calendar days after receipt. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit with Technical Proposal. 13. The contractor shall incorporate USG comments and resubmit to the USG within 10 calendar days after receipt. Resubmit for any changes to key personnel. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: (b) (6) and the Contracting Officer** (KO), (b) (6) LT: Letter of Transmittal (via email).	ASPR BARDA* CCAP SCN**	1 0	1 LT	0 0
15. TOTAL ▶ 1 1 0				

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

G. PREPARED BY (b) (6)	H. DATE 2/5/2021	I. APPROVED BY (b) (6)	J. DATE 2/5/2021
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CONTRACT DATA REQUIREMENTS LIST
(2 Data Items)

Form Approved
OMB No. 0704-0188

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

A. CONTRACT LINE ITEM NO. 0002	B. EXHIBIT A	C. CATEGORY: TDP _____ TM _____ OTHER <u>General/Admin Data</u>
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D. SYSTEM/ITEM LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE	E. CONTRACT/PR NO. W911QY-20-C-0100	F. CONTRACTOR ModernaUS, Inc.
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1. DATA ITEM NO. A009	2. TITLE OF DATA ITEM Contract Summary Report	3. SUBTITLE Final Technical Report
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4. AUTHORITY (Data Acquisition Document No.) DI-ADMN-80447A	5. CONTRACT REFERENCE C.4.7	6. REQUIRING OFFICE ASPR BARDA
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7. DD 250 REQ NA	9. DIST STATEMENT REQUIRED C	10. FREQUENCY R/ASR	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION		
8. APP CODE A		11. AS OF DATE 0	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES	
					Draft	Final

16. REMARKS 4 The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ The final report shall be marked as 'Final' A cover letter with the report shall contain a summary (not to exceed 200 words) of salient results achieved during the performance of the contract and be structured in the following format: Include the following: Identify doses accepted by the Government in previous submissions a Cover page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address and submission date b SECTION I: EXECUTIVE SUMMARY - Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work c SECTION II: RESULTS - A detailed description of the work performed related to WBS and Gantt chart, the results obtained, and the impact of the results on the scientific and/or public health community including a listing of all manuscripts (published and in preparation) and abstracts presented during the entire period of performance and a summary of all inventions 8 The US Government (USG) will respond with comments or approval within 30 calendar days after receipt of first draft report and within 15 calendar days of second submission 9 Distribution Statement C: Distribution authorized to U S Government agencies and their Contractors (Administrative or Operational Use) Determination made July 18, 2020 Distribution guidance is included in DoD Instruction 5230 24 12 Submit Draft Report 75 calendar days prior to end of contract Submit Final Report 30 calendar days after completion of contract 13 The contractor shall incorporate USG comments and resubmit to the USG within 30 calendar days after receipt for first submission and within 10 calendars days after second submission 14 Submit as an electronic file in Microsoft Office (i e Word, Excel, Power Point) via email to the BARDA representative: (b) (6) and the Contracting Officer** (KO), (b) (6) LT: Letter of Transmittal (via email)						
15. TOTAL →						
				2	2	0

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

1. DATA ITEM NO. A010	2. TITLE OF DATA ITEM Supply Chain Risk Management Plan	3. SUBTITLE Supply Chain Resiliency Plan (SCRIP)
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4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-82256	5. CONTRACT REFERENCE C.4.8	6. REQUIRING OFFICE ASPR BARDA
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7. DD 250 REQ NA	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION		
8. APP CODE A		11. AS OF DATE 0	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES	
					Draft	Final

16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . SPECIFIC CONTENT INSTRUCTIONS ARE PROVIDED AT ATTACHMENT 0001 TO THIS CDRL. 8. The US Government (USG) will respond with comments or approval within 10 calendar days after receipt. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit with 30 Calendar days after contract award. 13. The contractor shall incorporate USG comments and resubmit to the USG within 7 calendar days after receipt. Submit any and all proposed revisions to the Plan for USG approval 10 calendar days prior to implementation. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: (b) (6) and the Contracting Officer** (KO), (b) (6) LT: Letter of Transmittal (via email).						
15. TOTAL ▶						
				1	1	0

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

G. PREPARED BY (b) (6)	H. DATE 2/5/2021	I. APPROVED BY (b) (6)	J. DATE 2/5/2021
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CONTRACT DATA REQUIREMENTS LIST
(2 Data Items)

Form Approved
OMB No. 0704-0188

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

A. CONTRACT LINE ITEM NO. 0002	B. EXHIBIT A	C. CATEGORY: TDP _____ TM _____ OTHER <u>General/Admin Data</u>
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D. SYSTEM/ITEM LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE	E. CONTRACT/PR NO. W911QY-20-C-0100	F. CONTRACTOR ModernaUS, Inc.
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1. DATA ITEM NO. A013	2. TITLE OF DATA ITEM Research and Development of Medical Products Regulated by the U.S. Food and Drug Administration	3. SUBTITLE Manufacturing Reports and Dose Tracking Projections/Actuals
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4. AUTHORITY (Data Acquisition Document No.) DI-SESS-81309	5. CONTRACT REFERENCE C.4.10	6. REQUIRING OFFICE ASPR BARDA
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7. DD 250 REQ NA	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION		
8. APP CODE A		11. AS OF DATE NA	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES	
					Draft	Final

16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . Pg 10, paragraph e applies. The contractor shall complete the Dose Tracking Template provided at Attachment 0003. 8. The US Government (USG) will respond with comments or approval within 15 business days after receipt. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit Manufacturing Reports 15 business days prior to FDA submission. Submit the Dose Tracking Template within 15 calendar days after contract award and daily thereafter. 13. The contractor shall incorporate USG comments and resubmit to the USG within 5 business days after receipt. 14. Submit as an electronic file in Microsoft Excel via email to the BARDA representative: (b) (6) and the Contracting Officer** (KO), (b) (6) LT: Letter of Transmittal (via email).	15. TOTAL →	0	1	0
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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

1. DATA ITEM NO. A014	2. TITLE OF DATA ITEM Research and Development of Medical Products Regulated by the U.S. Food and Drug Administration	3. SUBTITLE Product Acceptance Report and Certificates of Analyses/Compliance
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4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040	5. CONTRACT REFERENCE C.4.11	6. REQUIRING OFFICE ASPR BARDA
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7. DD 250 REQ NA	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION		
8. APP CODE A		11. AS OF DATE NA	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES	
					Draft	Final

16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . The contractor shall provide: pictures of the drug product with lot number, drug product lot tree, and a Certificate of Analysis/Compliance. 8. The US Government (USG) will respond with comments or approval within 5 calendar days after receipt. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit for each lot of FDP delivered. 13. The contractor shall incorporate USG comments and resubmit to the USG within 3 calendar days after receipt. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: Marva Taylor (Marva.Taylor@hhs.gov) and the Contracting Officer** (KO), Christine Sordillo (christine.f.sordillo.civ@mail.mil). LT: Letter of Transmittal (via email).	15. TOTAL ▶	1	1	0
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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

G. PREPARED BY (b) (6)	H. DATE 2/5/2021	I. APPROVED BY (b) (6)	J. DATE 2/5/2021
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CONTRACT DATA REQUIREMENTS LIST
(2 Data Items)

Form Approved
OMB No. 0704-0188

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A. CONTRACT LINE ITEM NO. 0002	B. EXHIBIT A	C. CATEGORY: TDP _____ TM _____ OTHER <u>General/Admin Data</u>
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D. SYSTEM/ITEM LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE	E. CONTRACT/PR NO. W911QY-20-C-0100	F. CONTRACTOR ModernaUS, Inc.
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1. DATA ITEM NO. A015	2. TITLE OF DATA ITEM NOT USED	3. SUBTITLE
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4. AUTHORITY (Data Acquisition Document No.)	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
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7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION	14. DISTRIBUTION		
8. APP CODE		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION	a. ADDRESSEE	b. COPIES	
					Draft	Final
					Reg	Repro

16. REMARKS NOT USED	15. TOTAL →
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1. DATA ITEM NO. A016	2. TITLE OF DATA ITEM Accident Incident Report	3. SUBTITLE Incident Report
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4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-82188	5. CONTRACT REFERENCE C.4.12	6. REQUIRING OFFICE ASPR BARDA
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7. DD 250 REQ NA	9. DIST STATEMENT REQUIRED	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION		
8. APP CODE A	C	11. AS OF DATE NA	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES	
					Draft	Final
					Reg	Repro

16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit with 48 hours of activity or incident or within 24 hours for a security activity or incident. 13. Submit additional updates within 48 hours of additional developments. If corrective action is deemed necessary by the USG, the Contractor shall address in writing, its consideration of concerns raised within 5 business days of receipt. 14. Provide via telephone with written follow-ups and corrective actions to the COR and Contracting Officer. Provide write-up as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: (b) (6) and the Contracting Officer** (KO), (b) (6) LT: Letter of Transmittal (via email).	15. TOTAL ▶
	1 1 0

G. PREPARED BY (b) (6)	H. DATE 2/5/2021	I. APPROVED BY (b) (6)	J. DATE 2/5/2021
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17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST
(2 Data Items)

Form Approved
OMB No. 0704-0188

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A. CONTRACT LINE ITEM NO. 0002	B. EXHIBIT A	C. CATEGORY: TDP _____ TM _____ OTHER <u>General/Admin Data</u>
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D. SYSTEM/ITEM LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE	E. CONTRACT/PR NO. W911QY-20-C-0100	F. CONTRACTOR ModernaUS, Inc.
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1. DATA ITEM NO. A017	2. TITLE OF DATA ITEM Research and Development of Medical Products Regulated by the U.S. Food and Drug Administration	3. SUBTITLE FDA Correspondence
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4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040 (Tailored)	5. CONTRACT REFERENCE C.4.13	6. REQUIRING OFFICE ASPR BARDA
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7. DD 250 REQ NA	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION		
8. APP CODE A		11. AS OF DATE 0	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES	
					Draft	Final

16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . 8. The US Government (USG) will respond with comments or approval within 10 business days after receipt. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit within 2 business days of receipt of FDA correspondence. 13. The contractor shall incorporate USG comments and resubmit concurrent with FDA submission or no later than 1 calendar day of its submission to FDA. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: (b) (6) and the Contracting Officer** (KO), (b) (6) and LT: Letter of Transmittal (via email).	ASPR BARDA**	0	1	0	
	CCAP-SCN	0	LT	0	
	15. TOTAL	→	0	1	0

1. DATA ITEM NO. A018	2. TITLE OF DATA ITEM Acquisition Support Documentation	3. SUBTITLE Press Releases
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4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-81607	5. CONTRACT REFERENCE C.4.14	6. REQUIRING OFFICE ASPR BARDA
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7. DD 250 REQ NA	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION		
8. APP CODE A		11. AS OF DATE 0	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES	
					Draft	Final

16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . Only paragraphs 3.e, 3.f and 3.g apply. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit no less than 5 business days prior to the issuance of the press release. 13. Submit any final press releases no later than one (1) calendar day prior to its release. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: (b) (6) and the Contracting Officer** (KO), (b) (6) and LT: Letter of Transmittal (via email).	ASPR BARDA*	1	1	0	
	CCAP-SCN**	LT	LT	0	
	15. TOTAL	▶	1	1	0

G. PREPARED BY (b) (6)	H. DATE 2/5/2021	I. APPROVED BY (b) (6)	J. DATE 2/5/2021
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17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST
(2 Data Items)

Form Approved
OMB No. 0704-0188

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A. CONTRACT LINE ITEM NO. 0002	B. EXHIBIT A	C. CATEGORY: TDP _____ TM _____ OTHER <u>General/Admin Data</u>
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D. SYSTEM/ITEM LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE	E. CONTRACT/PR NO. W911QY-20-C-0100	F. CONTRACTOR ModernaUS, Inc.
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1. DATA ITEM NO. A023	2. TITLE OF DATA ITEM NOT USED	3. SUBTITLE
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4. AUTHORITY (Data Acquisition Document No.)	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
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7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION	14. DISTRIBUTION			
8. APP CODE		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION	a. ADDRESSEE		b. COPIES	
						Draft	Final
						Reg	Repro

16. REMARKS NOT USED	15. TOTAL →
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1. DATA ITEM NO. A024	2. TITLE OF DATA ITEM Operations Security (OPSEC) Plan	3. SUBTITLE Operational Security Plan (OPSEC) SOP/Plan
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4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-80934C	5. CONTRACT REFERENCE C.6.3	6. REQUIRING OFFICE ASPR BARDA
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7. DD 250 REQ NA	9. DIST STATEMENT REQUIRED	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION			
8. APP CODE A	C	11. AS OF DATE 0	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE		b. COPIES	
						Draft	Final
						Reg	Repro

16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . 8. The US Government (USG) will respond with comments or approval within 10 calendar days after receipt. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit within 90 calendar days of contract award. 13. The contractor shall incorporate USG comments and revisions within 10 calendar days after receipt. Resubmit for any revisions to the UGS-approved SOP/Plan. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: (b) (6) and the Contracting Officer** (KO), (b) (6) LT: Letter of Transmittal (via email).	15. TOTAL ▶			
		1	2	0

G. PREPARED BY (b) (6)	H. DATE 2/5/2021	I. APPROVED BY (b) (6)	J. DATE 2/5/2021
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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

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 Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0701-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. 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 address. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.

A. CONTRACT LINE ITEM NO. 0002	B. EXHIBIT A	C. CATEGORY: TDP _____ TM _____ OTHER <u>General/Admin Data</u>
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D. SYSTEM/ITEM LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE	E. CONTRACT/PR NO. W911QY-20-C-0100	F. CONTRACTOR ModernaUS, Inc.
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1. DATA ITEM NO. A025	2. TITLE OF DATA ITEM Research and Development of Medical Products Regulated by the U.S. Food & Drug Administration (FDA)	3. SUBTITLE Manufacturing Development Plan
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4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040	5. CONTRACT REFERENCE C.4.15	6. REQUIRING OFFICE ASPR BARDA
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7. DD 250 REQ NA	9. DIST STATEMENT REQUIRED C	10. FREQUENCY	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION		
8. APP CODE A		11. AS OF DATE 0	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES	
					Draft	Final
					Reg	Repro

16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . 8. The US Government (USG) will respond with comments or approval within 10 calendar days after receipt. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit within 30 calendar days of contract award. 13. The contractor shall incorporate USG comments and revisions within 10 calendar days after receipt. Resubmit for any revisions to the UGS-approved Plan. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: (b) (6) and the Contracting Officer** (KO), (b) (6) LT: Letter of Transmittal (via email).	ASPR BARDA*	1	1	0
	CCAP-SCN**	1	1	0
15. TOTAL	→	2	2	0

G. PREPARED BY (b) (6)	H. DATE 2020	I. APPROVED BY (b) (6)	J. DATE 2020
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17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

INSTRUCTIONS FOR COMPLETING DD FORM 1423

(See DoD 5010.12-M for detailed instructions.)

FOR GOVERNMENT PERSONNEL

- Item A.** Self-explanatory.
- Item B.** Self-explanatory.
- Item C.** Mark (X) appropriate category: TDP - Technical Data Package; TM - Technical Manual; Other - other category of data, such as "Provisioning," "Configuration Management," etc.
- Item D.** Enter name of system/item being acquired that data will support.
- Item E.** Self-explanatory (to be filled in after contract award).
- Item F.** Self-explanatory (to be filled in after contract award).
- Item G.** Signature of preparer of CDRL.
- Item H.** Date CDRL was prepared.
- Item I.** Signature of CDRL approval authority.
- Item J.** Date CDRL was approved.
- Item 1.** See DoD FAR Supplement Subpart 4.71 for proper numbering.
- Item 2.** Enter title as it appears on data acquisition document cited in Item 4.
- Item 3.** Enter subtitle of data item for further definition of data item (optional entry).
- Item 4.** Enter Data Item Description (DID) number, military specification number, or military standard number listed in DoD 5010.12-L (AMSDL), or one-time DID number, that defines data content and format requirements.
- Item 5.** Enter reference to tasking in contract that generates requirement for the data item (e.g., Statement of Work paragraph number).
- Item 6.** Enter technical office responsible for ensuring adequacy of the data item.
- Item 7.** Specify requirement for inspection/acceptance of the data item by the Government.
- Item 8.** Specify requirement for approval of a draft before preparation of the final data item.
- Item 9.** For technical data, specify requirement for contractor to mark the appropriate distribution statement on the data (ref. DoDD 5230.24).
- Item 10.** Specify number of times data items are to be delivered.
- Item 11.** Specify as-of date of data item, when applicable.
- Item 12.** Specify when first submittal is required.
- Item 13.** Specify when subsequent submittals are required, when applicable.
- Item 14.** Enter addressees and number of draft/final copies to be delivered to each addressee. Explain reproducible copies in Item 16.
- Item 15.** Enter total number of draft/final copies to be delivered.
- Item 16.** Use for additional/clarifying information for Items 1 through 15. Examples are: Tailoring of documents cited in Item 4; Clarification of submittal dates in Items 12 and 13; Explanation of reproducible copies in Item 14.; Desired medium for delivery of the data item.

FOR THE CONTRACTOR

Item 17. Specify appropriate price group from one of the following groups of effort in developing estimated prices for each data item listed on the DD Form 1423.

a. Group I. Definition - Data which is not otherwise essential to the contractor's performance of the primary contracted effort (production, development, testing, and administration) but which is required by DD Form 1423.

Estimated Price - Costs to be included under Group I are those applicable to preparing and assembling the data item in conformance with Government requirements, and the administration and other expenses related to reproducing and delivering such data items to the Government.

b. Group II. Definition - Data which is essential to the performance of the primary contracted effort but the contractor is required to perform additional work to conform to Government requirements with regard to depth of content, format, frequency of submittal, preparation, control, or quality of the data item.

Estimated Price - Costs to be included under Group II are those incurred over and above the cost of the essential data item without conforming to Government requirements, and the administrative and other expenses related to reproducing and delivering such data item to the Government.

c. Group III. Definition - Data which the contractor must develop for his internal use in performance of the primary contracted effort and does not require any substantial change to conform to Government requirements with regard to depth of content, format, frequency of submittal, preparation, control, and quality of the data item.

Estimated Price - Costs to be included under Group III are the administrative and other expenses related to reproducing and delivering such data item to the Government.

d. Group IV. Definition - Data which is developed by the contractor as part of his normal operating procedures and his effort in supplying these data to the Government is minimal.

Estimated Price - Group IV items should normally be shown on the DD Form 1423 at no cost.

Item 18. For each data item, enter an amount equal to that portion of the total price which is estimated to be attributable to the production or development for the Government of that item of data. These estimated data prices shall be developed only from those costs which will be incurred as a direct result of the requirement to supply the data, over and above those costs which would otherwise be incurred in performance of the contract if no data were required. The estimated data prices shall not include any amount for rights in data. The Government's right to use the data shall be governed by the pertinent provisions of the contract.