

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS
OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, AND 30

1. REQUISITION NUMBER
001155540

PAGE 1 OF 54

2 CONTRACT NO.
W911QY20C0119

3 AWARD/EFFECTIVE DATE
30-Sep-2020

4 ORDER NUMBER

5 SOLICITATION NUMBER

6 SOLICITATION ISSUE DATE

7 FOR SOLICITATION INFORMATION CALL:

a NAME

b TELEPHONE NUMBER (No Collect Calls)

8 OFFER DUE DATE/LOCAL TIME

9. ISSUED BY CODE **W911QY**

W6QK ACC-APG NATICK DIVISION
BLDG 1 GENERAL GREENE AVENUE
NATICK MA 01760-5011

TEL:

FAX: 508-233-5700

10. THIS ACQUISITION IS UNRESTRICTED OR SET ASIDE: _____ % FOR:

SMALL BUSINESS WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM

HUBZONE SMALL BUSINESS EDWOSB NAICS: 325412

SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS 8(A) SIZE STANDARD: 1,250

11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED SEE SCHEDULE

12. DISCOUNT TERMS

13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)

13b. RATING

14. METHOD OF SOLICITATION RFQ IFB RFP

15. DELIVER TO CODE **W902Q2**

JPEO-CBRND
(b) (6)
8222 HOADLEY RD E5101
ABERDEEN PROVING GROUND MD 21010

16. ADMINISTERED BY CODE

SEE ITEM 9

17a. CONTRACTOR/ OFFEROR CODE **36WK2** FACILITY CODE **36WK2**

ASTRAZENECA PHARMACEUTICALS LP
(b) (6)
1800 CONCORD PIKE
WILMINGTON DE 19803-2902
TELEPHONE NO. (b) (6)

18a. PAYMENT WILL BE MADE BY CODE **HQ0490**

DEFENSE FINANCE AND ACCOUNTING SERVICE
DFAS-INDY VP GFEB5
8899 E 56TH STREET
INDIANAPOLIS IN 46249-3800

17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER

18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a. UNLESS BLOCK BELOW IS CHECKED SEE ADDENDUM

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/ SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
SEE SCHEDULE					

25. ACCOUNTING AND APPROPRIATION DATA

See Schedule

26. TOTAL AWARD AMOUNT (For Govt. Use Only)

(b) (4)

27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4, FAR 52.212-3, 52.212-5 ARE ATTACHED. ADDENDA ARE ARE NOT ATTACHED

27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4, FAR 52.212-5 IS ATTACHED. ADDENDA ARE ARE NOT ATTACHED

28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 0 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.

29. AWARD OF CONTRACT: REF. A2D7442 OFFER DATED 09-Sep-2020. YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS: SEE SCHEDULE

30a. SIGNATURE OF OFFEROR/CONTRACTOR

(b) (6)

31a. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER)

(b) (6)

30b. NAME AND TITLE OF SIGNER (TYPE OR PRINT)

(b) (6)

30c. DATE SIGNED

9/30/2020

31b. NAME OF CONTRACTING OFFICER (TYPE OR PRINT)

TEL: **(b) (6)**

EMAIL: **(b) (6)**

31c. DATE SIGNED

30-Sep-2020

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS <i>OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, AND 30</i>				1. REQUISITION NUMBER 0011555540		PAGE 1 OF 54				
2. CONTRACT NO. W911QY20C0119		3. AWARD/EFFECTIVE DATE 30-Sep-2020		4. ORDER NUMBER		5. SOLICITATION NUMBER		6. SOLICITATION ISSUE DATE		
7. FOR SOLICITATION INFORMATION CALL:		a. NAME				b. TELEPHONE NUMBER (No Collect Calls)		8. OFFER DUE DATE/LOCAL TIME		
9. ISSUED BY W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011 TEL: FAX: 508-233-5700		CODE W911QY		10. THIS ACQUISITION IS <input checked="" type="checkbox"/> UNRESTRICTED OR <input type="checkbox"/> SET ASIDE: _____ % FOR: <input type="checkbox"/> SMALL BUSINESS <input type="checkbox"/> WOMEN-OWNED SMALL BUSINESS (WOSB) <input type="checkbox"/> HUBZONE SMALL BUSINESS <input type="checkbox"/> ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM <input type="checkbox"/> SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS <input type="checkbox"/> EDWOSB <input type="checkbox"/> 8(A) NAICS: 325412 SIZE STANDARD: 1,250						
11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED <input type="checkbox"/> SEE SCHEDULE		12. DISCOUNT TERMS		<input type="checkbox"/> 13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		13b. RATING				
15. DELIVER TO JPEO-CBRND (b) (6) 8222 HOADLEY RD E5101 ABERDEEN PROVING GROUND MD 21010		CODE W90ZQ2		16. ADMINISTERED BY SEE ITEM 9						
17a. CONTRACTOR/OFFEROR ASTRAZENECA PHARMACEUTICALS LP (b) (6) 1800 CONCORD PIKE WILMINGTON DE 19803-2902 TELEPHONE NO (b) (6)		CODE 36WK2		FACILITY CODE 36WK2		18a. PAYMENT WILL BE MADE BY DEFENSE FINANCE AND ACCOUNTING SERVICE DFAS-INDY VP GFEB5 8899 E 56TH STREET INDIANAPOLIS IN 46249-3800 CODE HQ0490				
<input type="checkbox"/> 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER				18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a. UNLESS BLOCK BELOW IS CHECKED <input checked="" type="checkbox"/> SEE ADDENDUM						
19. ITEM NO.		20. SCHEDULE OF SUPPLIES/ SERVICES				21. QUANTITY		22. UNIT	23. UNIT PRICE	24. AMOUNT
		SEE SCHEDULE								
25. ACCOUNTING AND APPROPRIATION DATA See Schedule						26. TOTAL AWARD AMOUNT (For Govt. Use Only) (b) (4)				
<input type="checkbox"/> 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1. 52.212-4. FAR 52.212-3. 52.212-5 ARE ATTACHED. ADDENDA <input type="checkbox"/> ARE <input type="checkbox"/> ARE NOT ATTACHED						<input type="checkbox"/> 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA <input type="checkbox"/> ARE <input type="checkbox"/> ARE NOT ATTACHED				
<input type="checkbox"/> 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 0 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.						<input checked="" type="checkbox"/> 29. AWARD OF CONTRACT: REF. AZD7442 OFFER DATED 09-Sep-2020 . YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS: SEE SCHEDULE				
30a. SIGNATURE OF OFFEROR/CONTRACTOR				31a. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER) (b) (6)						
30b. NAME AND TITLE OF SIGNER (TYPE OR PRINT)		30c. DATE SIGNED		31b. NAME OF CONTRACTING OFFICER (TYPE OR PRINT) (b) (6) (b) (6) (b) (6)				31c. DATE SIGNED 30-Sep-2020		

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

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

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

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE	32c. DATE	32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE
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32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE	32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE
	32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE

33. SHIP NUMBER <input type="checkbox"/> PARTIAL <input type="checkbox"/> FINAL	34. VOUCHER NUMBER	35. AMOUNT VERIFIED CORRECT FOR	36. PAYMENT <input type="checkbox"/> COMPLETE <input type="checkbox"/> PARTIAL <input type="checkbox"/> FINAL	37. CHECK NUMBER
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38. S/R ACCOUNT NUMBER	39. S/R VOUCHER NUMBER	40. PAID BY
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41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT	42a. RECEIVED BY (<i>Print</i>)		
41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER	41c. DATE	42b. RECEIVED AT (<i>Location</i>)	
		42c. DATE REC'D (<i>YY/MM/DD</i>)	42d. TOTAL CONTAINERS

Section SF 1449 - CONTINUATION SHEET

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	SARS-CoV-2 Therapeutic AZD7442 FFP The contractor shall provide SARS-CoV-2 therapeutic AZD7442 All required work shall be IAW the SOW and Commercial Solution Proposal titled "AZD7442 JPEO CSO Technical Volume_revised 09Sep", dated September 9, 2020. FOB: Destination PSC CD: 6550	100,000	Each	(b) (4)	(b) (4)

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000101	ACRN AA @ FFP PURCHASE REQUEST NUMBER: 0011555540				\$0.00

NET AMT \$0.00

ACRN AA (b) (4)
CIN: GFEB001155554000001

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002	Technical Data Deliverables FFP The contractor shall deliver technical data IAW the contract data deliverables listed within this contract. The contractor may consolidate reporting where applicable across its contracts with ACC-APG Natick for SARS-CoV-2 Therapeutic AZD7442. Consolidated reporting must be submitted to all POC's listed in each of the contracts. FOB: Destination PSC CD: 6550				NSP

NET AMT

STATEMENT OF WORK

ADDENDUM: The following pages hereby supplements FAR 52.212-4

1. Background:

In December 2019, a novel (new) coronavirus known as SARS-CoV-2 (“the virus”) 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 Services (HHS) 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.

Under the President’s Operation Warp Speed Mission, HHS is leading a whole of nation effort with the primary goal to execute on a well-defined portfolio of COVID-19 Medical Countermeasures (MCM) candidates to maximize probability of having safe and effective diagnostics, therapeutics and vaccines as fast as possible for mass distribution. As such, JPEO-CBRND has an Area of Interest (AoI) for therapeutics manufacturing and fill-finish of advanced SARS-CoV-2 MCMs. Therapeutics manufacturing is expected to meet the necessary US Food and Drug Administration (FDA) requirements for beginning a Phase 3 clinical trial, and the product must be granted licensure or Emergency Use Authorization (EUA) by the FDA.

2. Objective:

The government seeks to acquire treatment courses of therapeutic MCMs against SARS-CoV-2 that are either direct acting antivirals or host directed therapeutics, which indirectly inhibit the coronavirus lifecycle. Manufacturing shall occur using Current Good Manufacturing Practices (cGMP) validated manufacturing processes for bulk drug substance and fill and finished drug product. The specific objective is the acquisition of a minimum of 100,000 treatment courses for a targeted US population by (b) (4) [REDACTED], to treat the US population indicated in the Offeror’s target population. The intent is “Large Scale production capability in a short period of time with little to no advance notice under the conditions for which the MCM is required.” Prior to purchase by the Government, the product must receive approval or clearance from the FDA for either an Emergency Use Authorization (EUA) under Section 564 of the Federal Food, Drug & Cosmetic Act, or a biologics license application under the provisions of §351(a) of the Public Health Service Act, to permit use and marketing of the product.

3. Tasks:

Task 1: Establish a quality agreement between the US Government and Offeror on requirements for the US Government to accept packaged drug product AZD7442 as a completed deliverable. Quality agreement must be negotiated within the (b) (4) of award and prior to Government acceptance of drug product.

Task 2: Provide within (b) (4) of award Product Development Source Material and Manufacturing Plan to fulfill the US Government order for AZD7442. The manufacturing plan should include all materials required for drug substance/active pharmaceutical ingredient manufacturing and finished drug product, an acquisition plan for acquiring necessary materials, all key subcontractors and manufacturing sites, and a detailed schedule for providing the final approved product AZD7442 to the US Government.

Task 3: Manufacture of the therapeutic product AZD7442 shall occur using an established manufacturing process for bulk drug substance and fill and finished drug product, with a ramp-up capacity plan that provides enough doses of AZD7442 to meet the desired number of treatment courses.

Task 4 – Storage

(b) (4)

Task 5 – Distribution

(b) (4)

Task 6 – Program Management Activities:

The offeror must establish the capacity in compliance with FDA cGMP regulations, and Biosafety Level standards if applicable. The offeror must be responsible for management of all activities, subcontractors, etc. to meet the goals of the contract, including holding routine meetings with USG, and completion of meeting minutes. On a monthly basis, the offeror(s) must provide a monthly report that includes capacity availability and utilization, as well as any issues that affect the operational availability of the reserved capacity.

4. AoI Deliverables:

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
01	Meetings		

01.1	Post Award Teleconference	The contractor shall complete an initial teleconference after contract award 1. Outline activities for the next 30 days 2. Discuss agenda items for the post- award Kickoff Meeting (01.2)	<ul style="list-style-type: none"> •Within one week of contract award •Contractor shall provide agenda and establish a teleconference number at least 3 business days in advance of the teleconference unless notified that JPEO-CBRND will supply one •COR edits/approves and instructs contractor to distribute agenda prior to meeting by at least 2 business days •Contractor provides meeting minutes to COR within 3 business days after the meeting •COR reviews, comments and approves minutes within 10 business days
01.2	Kickoff Meeting	The Contractor shall complete a Kickoff meeting after contract award	<ul style="list-style-type: none"> •Within a month of contract award, pending concurrence by the contracting officer •Contractor shall provide itinerary and agenda at least 5 business days in advance of site visit or virtual meeting •COR edits/approves and instructs contractor to distribute agenda prior to meeting by at least 3 business days •Contractor provides meeting minutes to COR within 3 business days after the meeting •COR reviews, comments, and approves minutes within 10 business days
01.3	Every 2 weeks Teleconference	The Contractor shall participate in teleconferences every 2 weeks, with JPEO-CBRND to discuss the performance on the contract. Meeting frequency can be increased as needed during the course of the project	<ul style="list-style-type: none"> •Contractor provides agenda to COR no later than 2 business days in advance of meeting •COR edits/approves and instructs contractor to distribute agenda prior to meeting •Contractor distributes agenda and presentation materials at least 24 hours in advance •Contractor provides meeting minutes to COR within 3 business days of the meeting •COR reviews, comments, and approves minutes within 6 business days
01.4	Quarterly Meetings	At the discretion of the government the Contractor shall hold recurring teleconference or face-to-face Project Review Meetings up to four per year either in Washington D.C or at work sites of the Contractor or sub-contractors. Face-to-face meetings shall alternate between Washington DC and Contractor, sub-contractor sites. The meetings will be	<ul style="list-style-type: none"> •Contractor shall provide itinerary and agenda at least 5 business days, and presentation materials at least 3 business days in advance of site visit •COR edits/approves and instructs contractor to distribute agenda prior to meeting by at least 3 business days •Contractor provides meeting minutes to COR within 3 business days after the meeting •COR reviews, comments, and approves minutes within 10 business days
CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates

		used to discuss contract progress in relation to the Program Management deliverables described below as well as study designs, technical, regulatory, and ethical aspects of the program.	
01.5	FDA Meetings	The Contractor shall forward the dates and times of any meeting with the FDA to JPEO-CBRND and make arrangements for appropriate JPEO-CBRND staff to attend the FDA meetings. JPEO-CBRND staff shall include up to a maximum of four people (typically COR and up to 3 subject matter experts)	<ul style="list-style-type: none"> • Contractor shall notify JPEO-CBRND of upcoming FDA meeting within (b) (4) of scheduling Type A, B or C meetings OR within (b) (4) of meeting occurrence for ad hoc meetings • The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to JPEO-CBRND within [redacted] of receipt
01.6	Daily check in with project staff for COVID-19 Contract	<p>Upon request of the Government, the Contractor shall participate in a daily check-in update with the project staff (via teleconference or email).</p> <p>The updates will address key cost, schedule and technical updates. Daily updates may be shared with senior Government leaders during the COVID-19 response and should be provided on a non-confidential basis, unless the update includes confidential information in which case Contractor shall provide the update in both confidential and non-confidential formats.</p> <p>Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the Government, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.</p>	<ul style="list-style-type: none"> • No agenda will be required for the meeting • No meeting minutes are required • Contractor will provide bulleted email updates following any call or in lieu of a call by 2PM for that day
02	Technical Reporting		
02.1 (Monthly)	Monthly & Annual Technical Progress Reports/Annual Meeting	The Monthly and Annual Technical Progress reports shall address each of the below items and be cross-referenced to the Work Breakdown Structure (WBS), Statement of Work (SOW), Integrated Master Schedule (IMS), and Contract Performance Report (CPR) – or as applicable	<ul style="list-style-type: none"> • Monthly Reports shall be submitted on the 20th day of the month covering the preceding month; Annual Reports submitted on the 30th calendar day of the month after each contract anniversary. Monthly progress reports are not required for the months when the Annual Report(s) are due, and Monthly/Annual Report(s) are not due during a month when the Final Report (final version, not draft) is due (see deliverable 02.4). The COR and CO will review
02.2 (Annual)		1. An Executive Summary highlighting the progress, issues and relevant manufacturing, non-clinical, clinical and	

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>regulatory activities. The Executive Summary should highlight only critical issues for that reporting period and resolution approach; limited to 2 pages</p> <p>2. JPEO-CBRND Contractor Clinical Trials Information Sheet – covering ongoing JPEO-CBRND -sponsored clinical studies. This form shall provide data on relevant activities during the period covered, by study site, including: cumulative enrollment; new enrollments; screen failures; patients dropped from study; AE and SAEs; activation or inactivation of study sites; investigator appointments or changes; and status of IRB/IEC review/approval/renewal</p> <p>3. Progress in meeting contract milestones organized by WBS, overall project assessment, problems encountered and recommended solutions. The reports shall detail the planned and actual progress during the period covered, explaining any differences between the two and the corrective steps</p> <p>4. A three-month rolling forecast of the key planned activities, referencing the WBS/IMS</p> <p>5. A tracking log of progress on regulatory submissions with the FDA number, description of submission, date of submission, status of submission and next steps</p> <p>6. Estimated and Actual Expenses</p> <p>a. This report shall also contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the % of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level. This section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors. If the COR and CO are satisfied that the contractor's reporting is sufficient to convey this information, this section may be waived.</p>	<p>the monthly reports with the Contractor and provide feedback</p> <ul style="list-style-type: none"> • Contractor shall provide FINAL versions of reports within 10 business days after receiving JPEO-CBRND comments/edits

02.3 (Draft)	Draft and Final Technical Progress Report	A draft and Final Technical Progress Report containing a summation of the work performed and the results obtained over the entire contract. This report shall be in sufficient detail to fully describe the	•The Draft Technical Progress Report shall be submitted (b) (4) before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP
02.4 (Final)			

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>progress achieved under all milestones. Report should contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained during the contract. Descriptions and rationale for activities and milestones that were not completed as planned should be provided. The draft report shall be duly marked as 'Draft'</p> <p>The Final Technical Progress Report incorporating feedback received from JPEO-CBRND and containing a summation of the work performed and the results obtained for the entire contract PoP. The final report shall document the results of the entire contract. The final report shall be duly marked as 'Final'. A cover letter with the report will contain a summary (not to exceed 200 words) of salient results achieved during the performance of the contract</p>	<ul style="list-style-type: none"> •COR will provide feedback on draft report within 15 calendar days of receipt, which the Contractor shall consider incorporating into the Final Report
02.5	FDA Manufacturing Reports	<p>At JPEO-CBRND's request, Contractor shall provide Manufacturing Reports to JPEO-CBRND for review and comment prior to submission to FDA</p> <p>The COR and CO reserve the right to request within the PoP a non-proprietary Manufacturing Report for distribution within the USG</p>	<ul style="list-style-type: none"> •Contractor will submit Manufacturing Reports at least (b) (4) prior to FDA submission •The Government will provide written comments to the manufacturing report within (b) (4) after the submission •If corrective action is recommended, Contractor must address all concerns raised by JPEO-CBRND in writing •Contractor shall consider revising reports to address JPEO-CBRND's concerns and/or recommendations prior to FDA submission
02.6	Product Development Source Material and Manufacturing Reports and Projections	<p>The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and location and nature of non-clinical and clinical study sites.</p> <p>The Contractor will provide manufacturing reports and manufacturing dose tracking projections/actuals utilizing the "COVID-19 Dose Tracking Templates" or similar, on any contract/agreement that is manufacturing product, including product for clinical trial use.</p>	<ul style="list-style-type: none"> •Contractor will submit Product Development Source Material Report <ul style="list-style-type: none"> ○ Within month of contract award ○ Within 30 days of substantive changes are made to sources and/or materials ○ Or on the 6th month contract anniversary. •Contractor will update the Dose Tracking Template weekly during manufacturing campaigns and daily during response operations (where a Public Health Emergency has been declared) and COVID-19 response, with the first deliverable submission within 15 days of award/modification. Updates to be provided weekly in advance of commercial-scale manufacturing and daily once material for use in response operations begins manufacture.

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			<ul style="list-style-type: none"> •The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission •If corrective action is recommended, Contractor must address all concerns raised by JPEO-CBRND in writing •Product Development and Source Material report to be submitted via spreadsheet; Dose Tracking can be completed via spreadsheet or other format (e.g. XML or JSON) as agreed to by USG and company.
02.7	Contractor Locations	The contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors.	<p>Contractor will submit Work Locations Report:</p> <ul style="list-style-type: none"> •Within (b) (4) of contract award •Within (b) (4) after a substantive location or capabilities change •Within (b) (4) of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO
2.8	Pandemic Management Plan	A pandemic facility and/or operational management plan including change procedures from normal to pandemic operations Contractor will prepare an operational plan to continue operations in the event of a declared pandemic emergency.	<p>Contractor will submit Pandemic Management Plan:</p> <ul style="list-style-type: none"> • Draft within (b) (4) of award • Final within (b) (4) of award
02.9	Final Data Submission Package	<p>Contractor must submit a data package consisting of all raw data produced under this contract. Data may be used by JPEO-CBRND for analysis, evaluation, shared with other agencies, or shared outside of the government consistent with FAR 52.227-14. This submission package must be delivered in a non-proprietary format.</p> <p>If clinical trial data is included, that data must be provided consistent with applicable privacy laws to protect personally identifiable information (PII).</p>	Contractor will submit at least (b) (4) prior to contract end date. Partial data-sets may also be requested for delivery prior to submission of the Final Data Submission Package.
02.10	Supplemental Technical	Upon request and also as part of deliverables the Contractor shall provide	Contractor shall provide the Technical Documents upon request from the CO or COR

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
	Documents, Raw Data, Tabulation Data (e.g., CDISC-compliant SDTM SAS XPT datasets), or Data Analysis (e.g., CDISC-compliant ADaM SAS XPT datasets)	raw data, Tabulation Data (e.g., CDISC-compliant SDTM SAS XPT datasets), or Data Analysis (e.g., CDISC-compliant ADaM SAS XPT datasets), or data report to JPEO-CBRND.	
02.11	Supply Chain and Distribution Tracking	<p>Distribution Concept of Operations. JPEO-CBRND, CDC, and MCM Manufacturers play an important role in the distribution of therapeutics to the American people under a nationwide response. JPEO-CBRND will work with the manufacturer to monitor what is in the manufacturing pipeline using the enclosed dose tracking templates (see above). JPEO-CBRND will relay final drug product information as it is being released to the CDC for allocation and ordering by state public health departments. (b) (4)</p> <p>[REDACTED]</p> <p>(b) (4)</p> <p>[REDACTED]</p>	<p>Provide the following information in order to coordinate the movement and delivery of vaccine product (b) (4)</p> <p>[REDACTED]</p> <p>(b) (4) (b) (4)</p>

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			(b) (4)
02.12	Manufacturing Development Plan	This plan shall describe ("describe the manufacturing process for the drug/biologic product to ensure conformity with §501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21 United States Code (USC) §351 (a)(2)(B)), regarding good manufacturing practices (GMP)), but is not limited to planned or completed drug substance studies; list of excipients and information to support the safety of excipients that, when appropriate, shall be cross-referenced; drug product and formulation development summary from initial concept through final design; physicochemical and biological properties; manufacturing process development and validation program documents; container closure system documents [description, choice, rationale]; microbiological attributes documents and plans; compatibility documents (e.g., precipitation); assay development and validation, stability plan; and any associated risks.")	<ul style="list-style-type: none"> Plan will be delivered electronically (b) (4) of contract award to the CO and COR
02.13	Quality Management Plan	Plan may include, but is not limited to the quality policy and objectives, management review, competencies and training, process document control, feedback, evaluation, corrective action and preventive action, process improvement, measurement, and data analysis processes. The framework is normally divided into infrastructure, senior management responsibility, resource management, lifecycle management, and quality management system evaluation	<ul style="list-style-type: none"> Plan will be delivered electronically (b) (4) of contract award to the CO and COR
02.14	Quality Agreement	Agreement will determine the conditions of acceptance by the USG of the purchased	<ul style="list-style-type: none"> Agreement will be signed by the USG and the manufacturer (b) (4) of contract award Agreement will be delivered electronically to

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		product. No product will be accepted by the USG until a quality agreement is in place.	the CO and COR
03	Audits		
03.1	JPEO-CBRND Audit	Contractor shall accommodate periodic or ad hoc site visits by JPEO-CBRND. If JPEO-CBRND, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to JPEO-CBRND	<ul style="list-style-type: none"> • If issues are identified during the audit, Contractor shall submit a report to JPEO-CBRND detailing the finding and corrective action(s) (b) (4) of the audit • COR and CO will review the report and provide a response to the Contractor (b) (4) • Once corrective action is completed, the Contractor will provide a final report to JPEO-CBRND
03.2	FDA Audits	In the event of an FDA inspection that occurs in relation to this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for JPEO-CBRND representative(s) to be present during the final debrief by the regulatory inspector	<ul style="list-style-type: none"> • Contractor shall notify CO and COR (b) (4) of a scheduled FDA audit or (b) (4) of an ad hoc site visit/audit if the FDA does not provide advanced notice • Contractor shall provide copies of any FDA audit report received from subcontractors that occurs as a result of this contract or for this product (b) (4) of receiving correspondence from the FDA or third party • Within (b) (4) of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified
03.3	QA Audits	JPEO-CBRND reserves the right to participate in QA audits performed by the contractor. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to JPEO-CBRND. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action	<ul style="list-style-type: none"> • Contractor shall notify CO and COR a minimum of (b) (4) in advance of upcoming, audits/site visits of subcontractors • Contractor shall notify the COR and CO (b) (4) of report completion. • COR and CO will review the report and provide a response to the Contractor with (b) (4)

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
03.4	Risk Management Plan (RMP)	<p>The Contractor shall provide an RMP that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance</p>	<ul style="list-style-type: none"> • A Draft is due (b) (4) within contract award; updates to the RMP are due concurrent with Monthly Technical Progress Reports. The contractor may choose to notify the government up to two times every three months if there are no changes from the prior submission, and not submit an update • JPEO-CBRND will provide Contractor with a list of concerns in response plan submitted • Contractor must address, in writing, all concerns raised by JPEO-CBRND within (b) (4) of Contractor's receipt of JPEO-CBRND's concerns
03.5	Integrated Master Schedule (IMS)	<p>The contractor shall provide an IMS that illustrates project tasks, dependencies, durations throughout the period of performance, and milestones (GO/NO-GO). The IMS must map to the WBS, and provide baseline, and actual or forecast dates for completion of tasks</p>	<ul style="list-style-type: none"> • The IMS is to be submitted in both PDF and Microsoft Project Form to the COR • The first Draft of the IMS is due (b) (4) within contract award • The Government will request revisions (b) (4), at which point the schedule baseline for the period of performance will be set • Thereafter an updated IMS is due concurrent with Monthly Technical Progress Reports • During a declared Public Health Emergency, the IMS is to be delivered (b) (4) contract award, updates are due (b) (4) and any significant change (b) (4) must be reported immediately to the COR and/or designee.
03.6	Deviation Notification and Mitigation Strategy	<p>Process for changing IMS activities associated with cost and schedule as baselined. Contractor shall notify JPEO-CBRND of significant proposed changes the IMS defined as (b) (4)</p> <p>Contractor shall provide a high level management strategy for risk mitigation</p>	<ul style="list-style-type: none"> • Due at least (b) (4) prior to the Contractor anticipating the need to implement changes
03.7	Incident Report	<p>Contractor shall communicate to JPEO-CBRND 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. (b) (4)</p> <p>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, must also be reported</p>	<ul style="list-style-type: none"> • Due within (b) (4) of activity or incident or within (b) (4) for a security activity or incident • Email or telephone with written follow-up to COR and CO • Additional updates due to COR and CO (b) (4) of additional developments • Contractor shall submit within (b) (4) a Corrective Action Plan (if deemed necessary by either party) to address any potential issues • If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by JPEO-CBRND within (b) (4) of receiving such concerns

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
09	Advanced R&D Products		
09.1	Technical Documents	Upon request, Contractor shall provide CO and COR with deliverables from the following contract funded activities: quality agreements between contractors and sub-contractors, process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The CO and COR reserve the right to request within the PoP a non-proprietary technical document for distribution within the Government	<ul style="list-style-type: none"> Contractor shall provide technical document within (b) (4) of CO or COR request. Contractor can request additional time on an as needed basis If corrective action is recommended, the Contractor must address, in writing, concerns raised by JPEO-CBRND in writing
09.2	Animal Model or Other Technology Transfer Package	Contractor shall provide Animal Model or Other Technology Transfer Package containing relevant methodology and data sufficient to enable other practitioners in the field to successfully replicate experimental conditions developed and tested with JPEO-CBRND support	<ul style="list-style-type: none"> Contractor shall provide a draft package (b) (4) of COR or CO request Contractor shall revise the package to address JPEO-CBRND's concerns, recommendations and/or requests for additional detail
09.3	Raw Data, Tabulation Data (e.g., CDISC-compliant SDTM SAS XPT datasets), or Data Analysis (e.g., CDISC-compliant ADaM SAS XPT datasets)	Contractor shall provide raw data, Tabulation Data (e.g., CDISC-compliant SDTM SAS XPT datasets), or Data Analysis (e.g., CDISC-compliant ADaM SAS XPT datasets), to JPEO-CBRND upon request	<ul style="list-style-type: none"> Contractor shall provide raw data, Tabulation Data (e.g., CDISC-compliant SDTM SAS XPT datasets), or Data Analysis (e.g., CDISC-compliant ADaM SAS XPT datasets) to CO and COR within (b) (4) of request
09.4	Publications	Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to JPEO-CBRND for review prior to submission. Acknowledgment of JPEO-CBRND funding must be included as noted in contract articles H.9 and H.24	<ul style="list-style-type: none"> Contractor must submit all manuscript or scientific meeting abstract to PO and CO prior to submission/presentation by (b) (4) for manuscripts and (b) (4) for abstracts or posters Contractor must address in writing all concerns raised by JPEO-CBRND in writing Final submissions shall be submitted to JPEO-CBRND (b) (4) of its submission
10	Regulatory Documents		
10.1	FDA Correspondence	The Contractor shall memorialize any correspondence between Contractor and FDA and submit to JPEO-CBRND	<ul style="list-style-type: none"> Contractor shall provide copies of any FDA correspondence within (b) (4) of correspondence
10.2	FDA Submissions	The Contractor shall provide JPEO-CBRND the opportunity to review and comment upon all draft submissions before submission to the FDA. Contractor shall provide JPEO-CBRND with an electronic copy of the final FDA	<ul style="list-style-type: none"> Contractor shall submit draft FDA submissions to JPEO-CBRND at least (b) (4) prior to FDA submission JPEO-CBRND will provide feedback to Contractor within (b) (4) of receipt

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		submission. All documents shall be duly marked as either "Draft" or "Final"	<ul style="list-style-type: none"> The Contractor must address, in writing, its consideration of all concerns raised by JPEO-CBRND prior to FDA submission Final FDA submissions shall be submitted to JPEO-CBRND (b) (4)
11	Press Releases	Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases	<ul style="list-style-type: none"> Contractor shall ensure that the CO has received and approved an advanced copy of any press release to this contract not less than (b) (4) prior to the issuance of the press release If corrective action is required, the Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases Any final press releases shall be submitted to JPEO-CBRND no later than (b) (4) prior to its release

2. Detailed Description of Select Contract Deliverables

A. Monthly and Annual Progress Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with this Article F of this contract, and in the Statement of Work, attached to this contract as Attachment 1 (SECTION J-List of Attachments).

i. Monthly Progress Report

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

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

The format should include:

- A cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission;
- SECTION I – EXECUTIVE SUMMARY
- SECTION II – PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g., evaluating, and managing subcontractor performance, and personnel changes).
- SECTION II Part C: TECHNICAL PROGRESS - For each activity related to Gantt chart, document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between

planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project.

- SECTION II Part D: PROPOSED WORK - A summary of work proposed related to Gantt chart for the next reporting period and preprints/reprints of papers and abstracts.
 - SECTION III: Estimated and Actual Expenses.
- a. This section of the report shall contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the % of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level.
 - b. This section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors.

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

ii. Annual Progress Report

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

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

Each Annual Progress Report shall include:

- A Cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and email address; and the date of submission;
 - SECTION I: EXECUTIVE SUMMARY - A brief overview of the work completed, and the major accomplishments achieved during the reporting period.
 - SECTION II: PROGRESS
 - SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
 - SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A high level summary of critical meetings, etc. that have taken place during the reporting period. Include progress on administration and management to critical factors of the project (e.g. regulatory compliance audits and key personnel changes).
 - SECTION II Part C: TECHNICAL PROGRESS - A detailed description of the work performed structured to follow the activities and decision gates outlined at the Integrated Baseline Review and as described in the Integrated Master Plan. The Report should include a description of any problems (technical or financial) that occurred or were identified during the reporting period, and how these problems were resolved.
 - SECTION II Part D: PROPOSED WORK - A summary of work proposed for the next year period to include an updated Gantt Chart.
 - SECTION III: Estimated and Actual Expenses.
- a. This section of the report shall contain a narrative or table detailing whether there were discrepancies between estimated and actual expenses over the past year. Actual expenses should be broken down to the appropriate WBS level. This section of the report should also contain estimates for outstanding costs for the previous year which may have been incurred, but not yet billed.

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

1. Copies of manuscripts (published and unpublished), abstracts, and any protocols or methods developed specifically under the contract during the reporting period; and

2. A summary of any Subject Inventions per the requirements under FAR Clause 52.227-11.

iii. Draft Final Report and Final Report

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

The report shall conform to the following format:

1. Cover page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address and submission date.
2. SECTION I: EXECUTIVE SUMMARY - Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.
3. SECTION II: RESULTS - A detailed description of the work performed related to WBS and Gantt chart, the results obtained, and the impact of the results on the scientific and/or public health community including a listing of all manuscripts (published and in preparation) and abstracts presented during the entire period of performance and a summary of all inventions.

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

Final Report: The Contractor will deliver the final version of the Final Report on or before the completion date of the contract. The final version shall include or address the COR's and CO's written comments on the draft report. Final Report shall be submitted on or before the completion date of the contract.

iv. Summary of Salient Results

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

v. Audit Reports

Within (b) (4) of an audit related to conformance to FDA regulations and guidance, including adherence to GLP, GMP, GCP guidelines, the Contractor shall provide copies of the audit report (so long as received from the FDA) and a plan for addressing areas of nonconformance to FDA regulations and guidelines for GLP, GMP, or GCP guidelines as identified in the final audit report.

vi. Other Technical Reports

1. Supplemental Technical Documents

Upon request, Contractor shall provide CO and COR with the following contract funded documents as specified below but not limited to: Process Development Reports; Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, Contractor/Subcontractor Standard Operating Procedures (SOP's), Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The CO and COR reserve the right to request within the Period of Performance a non-proprietary technical document for distribution within the USG. Contractor shall provide technical document within (b) (4) of CO or COR request. Contractor can request additional time on an as needed basis. If edits are recommended, the Contractor must address, in writing, concerns raised by JPEO-CBRND.

B. Deliverables Arising from FDA Correspondence

i. FDA Meetings

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

- Contractor shall notify JPEO-CBRND of upcoming FDA meeting within (b) (4) of scheduling Type A, B or C meetings OR within (b) (4) of meeting occurrence for ad hoc meetings.
- The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to JPEO-CBRND within (b) (4) of receipt. All documents shall be duly marked as either "Draft" or "Final."

ii. FDA Submissions

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

- When draft documents are submitted for JPEO-CBRND review, JPEO-CBRND will provide feedback to Contractor within (b) (4) of receipt.
- When JPEO-CBRND reviews draft documents, the Contractor shall revise their documents to address JPEO-CBRND's written concerns and/or recommendations prior to FDA submission.
- Final FDA submissions shall be submitted to JPEO-CBRND concurrently or no later than (b) (4) of their submission to FDA.

iii. FDA Audits

In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR) (b) (4) after the Contractors receipt of those documents. The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for JPEO-CBRND representative(s) to be present during the final debrief by the regulatory inspector.

- Contractor shall notify CO and COR within (b) (4) of a scheduled FDA audit or within (b) (4) of an ad hoc site visit/audit if the FDA does not provide advanced notice.
- Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within (b) (4) of receiving correspondence from the FDA, Subcontractor, or third party.
- Within (b) (4) of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.

iv. Manufacturing Campaign Reports

Contractor shall provide Manufacturing Campaign Reports to JPEO-CBRND for review and comment prior to submission to FDA.

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

- Contractor will submit Manufacturing Campaign Reports at least (b) (4) prior to FDA submission.
- If corrective action is recommended, Contractor must address, in writing, all concerns raised by JPEO-CBRND.
- Contractor shall revise the reports to address JPEO-CBRND’s concerns and/or recommendations prior to FDA submission.
- Final FDA submission shall be submitted to JPEO-CBRND concurrently or no later than (b) (4) after submission to the FDA.

v. Other FDA Correspondence

The Contractor shall memorialize any correspondence between Contractor and FDA and submit to JPEO-CBRND. All documents shall be duly marked as either “Draft” or “Final.” Contractor shall provide written summary of any FDA correspondence within (b) (4) of correspondence.

i. Risk Management Plan

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

- Due within (b) (4) of contract award
- Contractor provides updated Risk Management Plan in Monthly Progress Report
- JPEO-CBRND shall provide Contractor with a written list of concerns in response plan submitted
- Contractor must address, in writing, all concerns raised by JPEO-CBRND within (b) (4) of Contractor’s receipt of JPEO-CBRND’s concerns.

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
0001	(b) (4)	100,000	JPEO-CBRND (b) (6) 8222 HOADLEY RD E5101 ABERDEEN PROVING GROUND MD 21010 (b) (6) FOB: Destination	W90ZQ2
000101	N/A	N/A	N/A	N/A
0002	N/A	N/A	N/A	N/A

ADDITIONAL SHIPPING INFO

SECTION F DELIVERIES OR PERFORMANCE

F.1. The distribution plan is currently TBD. (b) (4)

F.2. Supply Chain Resiliency Plan: The contractor shall develop and submit within (b) (4) of contract award, a comprehensive Supply Chain Resiliency Program that provides identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods.

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

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

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

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

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

- a) Production rates and lead times shall be understood and communicated to the Contracting 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.

Reports for critical items should include the following information:

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

The CO and COR reserve the right to request un-redacted copies of technical documents, during the period of performance, for distribution within the Government. Documents shall be provided within (b) (4) after CO issues the request. The Contractor may arrange for additional time if deemed necessary, and agreed to by the CO.

F.3. Manufacturing Data Requirements: The Contractor shall submit within (b) (4) of contract award detailed data regarding project materials, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing, processing, and fill/finish sites; and location and nature of non-clinical and clinical studies sites. The Government may provide a table in tabular format for Contractor to be used to submit such data which would include but not be limited to the following:

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

F.4. Product Development Source Material and Manufacturing Reports and Projections: The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and location and nature of non-clinical and clinical study sites.

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

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

F.5. Contractor Locations: The contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors.

Contractor will submit Work Locations Report:

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

F.6. Access and General Protection/Security Policy and Procedures: This standard language text is applicable to ALL employees working on critical information related to Operation Warp Speed (OWS), and to those with an area of performance within a Government controlled installation, facility or area. Employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and

procedures (provided by government representative). The performer also shall provide all information required for background checks necessary to access critical information related to OWS, and to meet Government installation access requirements to be accomplished by installation Director of Emergency Services or Security Office. The workforce must comply with all personnel identity verification requirements as directed by the Government and/or local policy. In addition to the changes otherwise authorized by the changes clause of this agreement, should the security status of OWS change the Government may require changes in performer security matters or processes. In addition to the industry standards for employment background checks, The Contractor must be willing to have key individuals, in exceptionally sensitive positions, identified for additional vetting by the United States Government.

F.7. Operational Security (OPSEC): The performer shall develop an OPSEC Standard Operating Procedure (SOP)/Plan within ninety (90)-calendar-days of project award to be reviewed and approved by the responsible Government OPSEC officer. This plan will be submitted to the COR for coordination of approvals. This SOP/Plan will include identifying the critical information related to this contract, why it needs to be protected, where it is located, who is responsible for it, and how to protect it.

F.8. Security Plan: The contractor shall develop a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the Government requirement. This plan shall establish security practices and procedures that demonstrate how the contractor will meet and adhere to the security requirements outlined below prior to the commencement of product manufacturing, and shall be delivered to the Government within 30 calendar days of award. The contractor shall also ensure all subcontractors, consultants, researchers, etc. performing work on behalf of this effort, comply with all Government security requirements and prime contractor security plans.

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

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

Security Requirements:

1. Facility Security Plan	
Description: As part of the partner facility’s overall security program, the contractor shall submit a written security plan with their proposal to the Government for review and approval by Government security subject matter experts. The performance of work under the contract will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:	
Security Administration	<ul style="list-style-type: none"> organization chart and responsibilities written security risk assessment for site threat levels with identification matrix (High, Medium, or Low) enhanced security procedures during elevated threats liaison procedures with law enforcement annual employee security education and training program
Personnel Security	<ul style="list-style-type: none"> policies and procedures candidate recruitment process background investigations process employment suitability policy employee access determination rules of behavior/ conduct termination procedures non-disclosure agreements

Physical Security Policies and Procedures	<ul style="list-style-type: none"> internal/external access control protective services identification/badging
	<ul style="list-style-type: none"> employee and visitor access controls parking areas and access control perimeter fencing/barriers product shipping, receiving and transport security procedures facility security lighting restricted areas signage intrusion detection systems alarm monitoring/response closed circuit television product storage security other control measures as identified
Information Security	<ul style="list-style-type: none"> identification and marking of sensitive information access control storage of information document control procedures retention/ destruction requirements
Information Technology/Cyber Security Policies and Procedures	<ul style="list-style-type: none"> intrusion detection and prevention systems threat identification employee training (initial and annual) encryption systems identification of sensitive information/media password policy (max days 90) lock screen time out policy (minimum time 20 minutes) removable media policy laptop policy removal of IT assets for domestic/foreign travel access control and determination VPN procedures WiFi and Bluetooth disabled when not in use system document control system backup system disaster recovery incident response system audit procedures property accountability
<p>2. Site Security Master Plan Description: The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; IT Server Room; Product Storage Freezer/Room; and bio-containment laboratories.</p>	
<p>3. Site Threat / Vulnerability / Risk Assessment Description: The partner facility shall provide a written risk assessment for the facility addressing: criminal threat, including crime data; foreign/domestic terrorist threat; industrial espionage; insider threats; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies. The assessment should be updated annually.</p>	
<p>4. Physical Security Description:</p>	

Closed Circuit Television (CCTV) Monitoring	a) Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored.
	CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. Video recordings must be maintained for a minimum of 30 days. CCTV surveillance system must be on emergency power backup. CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. Video recordings must be maintained for a minimum of 30 days. CCTV surveillance system must be on emergency power backup.
Facility Lighting	Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings. Lighting must have emergency power backup. Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.
Shipping and Receiving	Must have CCTV coverage and an electronic access control system. Must have procedures in place to control access and movement of drivers picking up or delivering shipments. Must identify drivers picking up Government products by government issued photo identification.
Access Control	Must have an electronic intrusion detection system with centralized monitoring. Responses to alarms must be immediate and documented in writing. Employ an electronic system (i.e., card key) to control access to areas where assets critical to the contract are located (facilities, laboratories, clean rooms, production facilities, warehouses, server rooms, records storage, etc.). The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas. Must have a system that provides a historical log of all key access transactions and kept on record for a minimum of 12 months. Must have procedures in place to track issuance of access cards to employees and the ability to deactivate cards when they are lost or an employee leaves the company. Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of 12 months. Should have written procedures to prevent employee piggybacking access to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access. Must have a written manual key accountability and inventory process. Physical access controls should present a layered approach to critical assets within the facility.
Employee/Visitor Identification	Should issue company photo identification to all employees. Photo identification should be displayed above the waist anytime the employee is on company property. Visitors should be sponsored by an employee and must present government issued photo identification to enter the property. Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises at all times.

Security Fencing	Requirements for security fencing will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces	Requirements for security officers will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces Operations	Must have in-service training program. Must have Use of Force Continuum. Must have communication systems available (i.e., landline on post, cell phones, handheld radio, and desktop computer). Must have Standing Post Orders. Must wear distinct uniform identifying them as security officers.
5. Security Operations	
Description:	
Information Sharing	Establish formal liaison with law enforcement. Meet in person at a minimum annually. Document meeting notes and keep them on file for a, minimum of 12 months. POC information for LE Officer that attended the meeting must be documented. Implement procedures for receiving and disseminating threat information.
Training	Conduct new employee security awareness training. Conduct and maintain records of annual security awareness training.
Security Management	Designate a knowledgeable security professional to manage the security of the facility. Ensure subcontractor compliance with all Government security requirements.
6. Personnel Security	
Description:	
Records Checks	Verification of social security number, date of birth, citizenship, education credentials, five-year previous employment history, five-year previous residence history, FDA disbarment, sex offender registry, credit check based upon position within the company; motor vehicle records check as appropriate; and local/national criminal history search.
Hiring and Retention Standards	Detailed policies and procedures concerning hiring and retention of employees, employee conduct, and off boarding procedures. Off Boarding procedures should be accomplished within 24 hour of employee leaving the company. This includes termination of all network access.
7. Information Security	
Description:	
Physical Document Control	Applicable documents shall be identified and marked as procurement sensitive, proprietary, or with appropriate government markings. Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet/desk or other storage device and not be left unattended. Access to sensitive information should be restricted to those with a need to know.
Document Destruction	Documents must be destroyed using approved destruction measures (i.e, shredders/approved third party vendors / pulverizing / incinerating).
8. Information Technology & Cybersecurity	
Description:	

Identity Management	Physical devices and systems within the organization are inventoried and accounted for annually. Organizational cybersecurity policy is established and communicated. Asset vulnerabilities are identified and documented.
	Cyber threat intelligence is received from information sharing forums and sources. Threats, vulnerabilities, likelihoods, and impacts are used to determine risk. Identities and credentials are issued, managed, verified, revoked, and audited for authorized devices, users and processes. Users, devices, and other assets are authenticated (e.g., single-factor, multifactor) commensurate with the risk of the transaction (e.g., individuals' security and privacy risks and other organizational risks)
Access Control	Limit information system access to authorized users. Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access. Limit physical access to information systems, equipment, and server rooms with electronic access controls. Limit access to/ verify access to use of external information systems.
Training	Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.
Audit and Accountability	Create, protect, and retain information system audit records to the extent needed to enable the monitoring, analysis, investigation, and reporting of unlawful, unauthorized, or inappropriate system activity. Records must be kept for minimum must be kept for 12 months. Ensure the actions of individual information system users can be uniquely traced to those users. Update malicious code mechanisms when new releases are available. Perform periodic scans of the information system and real time scans of files from external sources as files are downloaded, opened, or executed.
Configuration Management	Establish and enforce security configuration settings. Implement sub networks for publically accessible system components that are physically or logically separated from internal networks.
Contingency Planning	a) Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times.
Incident Response	Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery of cybersecurity incidents. Exercise this capability annually.
Media and Information Protection	Protect information system media, both paper and digital. Limit access to information on information systems media to authorized users. Sanitize and destroy media no longer in use. Control the use of removable media through technology or policy.

Physical and Environmental Protection	Limit access to information systems, equipment, and the respective operating environments to authorized individuals. Intrusion detection and prevention system employed on IT networks. Protect the physical and support infrastructure for all information systems. Protect information systems against environmental hazards. Escort visitors and monitor visitor activity.
Network Protection	Employ intrusion prevention and detection technology with immediate analysis capabilities.
9. Transportation Security	
Description: Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage.	
Drivers	Drivers must be vetted in accordance with Government Personnel Security Requirements. Drivers must be trained on specific security and emergency procedures. Drivers must be equipped with backup communications. Driver identity must be 100 percent confirmed before the pick-up of any Government product. Drivers must never leave Government products unattended, and two drivers may be required for longer transport routes or critical products during times of emergency. Truck pickup and deliveries must be logged and kept on record for a minimum of 12 months.
Transport Routes	Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency. Transport routes should be continuously evaluated based upon new threats, significant planned events, weather, and other situations that may delay or disrupt transport.
Product Security	Government products must be secured with tamper resistant seals during transport, and the transport trailer must be locked and sealed. Tamper resistant seals must be verified as "secure" after the product is placed in the transport vehicle. Government products should be continually monitored by GPS technology while in transport, and any deviations from planned routes should be investigated and documented. Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.
10. Security Reporting Requirements	
Description: The partner facility shall notify the Government Security Team within 24 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of government products. The facts and circumstances associated with these incidents will be documented in writing for government review.	
11. Security Audits	
Description: The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and subcontractor.	

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Destination	Government	Destination	Government
000101	N/A	N/A	N/A	N/A
0002	Destination	Government	Destination	Government

ACCOUNTING AND APPROPRIATION DATA

AA: 09720202021013000018170552520252 S.0074658.1.1.15 6100.9000021001
 COST CODE: AHPDD
 AMOUNT: (b) (4)

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	000101	GFEB001155554000001	(b) (4)

CONTRACT ADMINISTRATION

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.

Contracting Officer:

(b) (6)

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

Procurement Specialist:

(b) (6)

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

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

G.2 Government Technical Points of Contact:

Program Manager:

(b) (6)

(b) (6) [Redacted]

G.3 Contractor’s Contract Administration

Technical Point of Contact:

(b) (6) [Redacted]

Administrative Point of Contact:

(b) (6) [Redacted]

G.4 Contractor’s Past Performance Point of Contact (POC):

Annual contract past performance evaluations will be performed by the government. The offeror shall identify a Point of Contact (POC) to participate in these on-line evaluations. This individual is required to register in the Contractor Performance Assessment Reporting System (CPARS @ <http://www.cpars.csd.disa.mil>) and respond to the government evaluations in a timely manner. The contractor POC responsible for this action is:

(b) (6) [Redacted]

G.5 Notifications of Revisions and Changes:

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.

TERMS AND CONDITIONS

SPECIAL CONTRACT REQUIREMENTS

H.1. The government hereby issues this contract action as an Unfinalized Contract Action (UCA) for the manufacturing therapeutic AZD7442 in support of OWS. The UCA award is being executed as a result of the MCM Commercial Solutions Opening (CSO) Solicitation W911QY-20-S-C001 Area of Interest (AOI) Number A003: SARS-CoV-2 Medical Counter Measures (MCM) Therapeutics.

H.1.1. This contract shall be definitized NLT 180 days from the date of this award as required by the CONTRACT DEFINITIZATION CLAUSE 252.217-7027. The government intends to obligate (b) (4) [Redacted] upon award of the UCA. The government has developed a definitization schedule that defines the milestone events required to definitize the contract sooner than the required 180 days. The government reserves the right to utilize up to the full 180 day for definitization as required.

H.1.2. The Government expects that the definitized contract shall include additional terms that at a minimum will include: a revised list of deliverables to more accurately reflect the final agreed-upon work to be performed; apportionment of technical data rights for subject data generated under this contract; and ensuring sufficient supply of the product to the Government.

H.2. 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:

Technical point of contact:

(b) (6)
 [Redacted]
 [Redacted]
 [Redacted]
 [Redacted]

Administrative point of contact:

(b) (6)
 [Redacted]
 [Redacted]
 (b) (6)
 [Redacted]

H.3. 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 guidance. 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.

The contractor further agrees to include the substance of this language in any subcontract, which may be awarded under this contract.

H.4. Contractor's Organization: The contractor's organization shall be established with authority to effectively accomplish the objectives of the Statement of Work. This organization shall become effective upon award of the contract and its integrity shall be maintained for the duration of the contract effort.

H.5. 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 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 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.

H.6. 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 government logos 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 government approval or endorsement of the product(s) or service(s) provided.
- (d) The contractor shall include this language, 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 government 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 by the U.S. government under Contract No. "W911QY-20-C-0101". The US government is authorized to reproduce and distribute reprints for governmental purposes notwithstanding any copyright notation thereon.

H.7. Confidentiality of Information:

- a. Confidential information, as used in this article, means 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 above requirements MUST be passed to all Sub-contractors.

H.8. Organizational Conflicts of Interest: Performance under this contract may create an actual or potential organizational conflict of interest such as are contemplated by FAR Part 9.505-General Rules. The contractor shall not engage in any other contractual or other activities which could create an organizational conflict of interest (OCI). This provision shall apply to the prime contractor and all sub-Contractors. This provision shall have effect throughout the period of performance of this contract, any extensions thereto by change order or supplemental agreement, and for two (2) years thereafter. The government may pursue such remedies as may be permitted by law or this contract, upon determination that an OCI has occurred.

The work performed under this contract may create a significant potential for certain conflicts of interest, as set forth in FAR Parts 9.505-1, 9.505-2, 9.505-3, and 9.505-4. It is the intention of the parties hereto to prevent both the potential for bias in connection with the Contractor's performance of this contract, as well as the creation of any unfair competitive advantage as a result of knowledge gained through access to any non-public data or third party proprietary information.

The contractor shall notify the Contracting Officer immediately whenever it becomes aware that such access or participation may result in any actual or potential OCI. Furthermore, the contractor shall promptly submit a plan to the Contracting Officer to either avoid or mitigate any such OCI. The Contracting Officer will have sole discretion in accepting the Contractor's mitigation plan. In the event the Contracting Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the contractor from participating in contract requirements related to OCI.

Whenever performance of this contract provides access to another Contractor's proprietary information, the contractor shall enter into a written agreement with the other entities involved, as appropriate, in order to protect such proprietary information from unauthorized use or disclosure for as long as it remains proprietary; and refrain from using such proprietary information other than as agreed to, for example to provide assistance during technical evaluation of other Contractors' offers or products under this contract. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the CO within fifteen (15) calendar days of execution.

H.9. Institutional Responsibility Regarding Investigator Conflicts of Interest: The Institution (includes any Contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under government contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any

Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site:
<http://www.ecfr.gov/cgi-bin/textidx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=>

As required by 45 CFR Part 94, the Institution shall, at a minimum:

a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. Included are payments and equity interests;
2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or
3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

Significant financial interests do not include the following:

1. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and
2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any government funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.

c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the government funded research.

d. Require that each Investigator who is planning to participate in the government funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for government funded research. Require that each Investigator who is participating in the government funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.

e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to government funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to government funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest: Could be affected by the government funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through

its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the government funded research.

- f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).
- g. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).
- h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.
- i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.
- j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Contractors titled "Certification of Institutional Policy on Financial Conflicts of Interest".
- k. If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the government funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the government funded research project.
- l. The Contracting Officer and/or government may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the government funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.
- m. If the Contracting Officer determines that government funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

H.10. Regulatory Rights and Compliance

Contractor is 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). Contractor has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

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

- a. The Contractor will provide to the Government all data including top-line summaries and key conclusions

from all studies supporting the regulatory filing and commercial approval to the extent that such data, summaries, and conclusions are funded by this Agreement. In addition, the Contractor will offer the Government the opportunity to review and provide comments on a final draft of regulatory submissions which include data funded by this Agreement. The Government will review any such submissions promptly upon receipt. The Contractor will reasonably consider any comments provided by the Government, and prior to submission will provide notification to the Government of any additional edits or revisions. The Contractor will keep the Government apprised of planned FDA meetings and post-meeting outcomes relating to activities funded by this Agreement.

b. The Contractor shall provide the Government with all formal and informal communications and summaries thereof to or from FDA, regarding the Technology within (b) (4), and use best efforts to ensure that the Government representatives are invited to participate in any formal or informal Sponsor meetings with FDA. Contractor shall (1) ensure that the Government representatives are consulted and are invited to participate in any formal or informal Sponsor meetings with FDA related to the Technology; and (2) notify the FDA that the Government has the right to discuss with FDA any development efforts regarding the Technology.

2. The manufacturing described in the Statement of Work will comply with Current Good Manufacturing Practices (cGMP) regulations at 21 CFR 210 and 211. Production shall occur using cGMP validated manufacturing process, fully compliant with 21 CFR 210 and 211, for bulk drug substance and fill and finished drug product, with a ramp-up capacity that provides doses sufficient for the government to treat the US population.

3. Production and distribution shall comply with applicable provisions of the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov 27, 2013), taking into account FDA's regular guidance for the COVID-19 public health response.

CLAUSES INCORPORATED BY REFERENCE

52.204-7	System for Award Management	OCT 2018
52.204-13	System for Award Management Maintenance	OCT 2018
52.204-21	Basic Safeguarding of Covered Contractor Information Systems	JUN 2016
52.204-24	Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment.	AUG 2020
52.212-3 Alt I	Offeror Representations and Certifications--Commercial Items (AUG 2020) Alternate I	OCT 2014
52.232-40	Providing Accelerated Payments to Small Business Subcontractors	DEC 2013
252.203-7000	Requirements Relating to Compensation of Former DoD Officials	SEP 2011
252.203-7003	Agency Office of the Inspector General	AUG 2019
252.204-7012	Safeguarding Covered Defense Information and Cyber Incident Reporting	DEC 2019
252.211-7003	Item Unique Identification and Valuation	MAR 2016
252.232-7003	Electronic Submission of Payment Requests and Receiving Reports	DEC 2018
252.232-7010	Levies on Contract Payments	DEC 2006
252.244-7000	Subcontracts for Commercial Items	JUN 2013

CLAUSES INCORPORATED BY FULL TEXT

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

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

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

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

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

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

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

(g) Invoice.

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

(i) Name and address of the Contractor;

(ii) Invoice date and number;

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) Payment.--

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

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

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

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

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

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

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

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

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

(D) Contractor point of contact.

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

(6) Interest.

(i) All amounts that become payable by the Contractor to the Government under this contract shall bear simple interest from the date due until paid unless paid within 30 days of becoming due. The interest rate shall be the interest rate established by the Secretary of the Treasury as provided in 41 U.S.C. 7109, which is applicable to the period in which the amount becomes due, as provided in (i)(6)(v) of this clause, and then at the rate applicable for each six-month period as fixed by the Secretary until the amount is paid.

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

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

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

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

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

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

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

(A) The date fixed under this contract.

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

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

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

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

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

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

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

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

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

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

(l) Termination for the Government's convenience. The Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

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

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

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

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

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

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

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

(t) Reserved.

(u) Unauthorized Obligations.

(1) Except as stated in paragraph (u)(2) of this clause, when any supply or service acquired under this contract is subject to any End User License Agreement (EULA), Terms of Service (TOS), or similar legal instrument or agreement, that includes any clause requiring the Government to indemnify the Contractor or any person or entity

for damages, costs, fees, or any other loss or liability that would create an Anti-Deficiency Act violation (31 U.S.C. 1341), the following shall govern:

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

(ii) Neither the Government nor any Government authorized end user shall be deemed to have agreed to such clause by virtue of it appearing in the EULA, TOS, or similar legal instrument or agreement. If the EULA, TOS, or similar legal instrument or agreement is invoked through an "I agree" click box or other comparable mechanism (e.g., "click-wrap" or "browse-wrap" agreements), execution does not bind the Government or any Government authorized end user to such clause.

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

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

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

(End of Clause)

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

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

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

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

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

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

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

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

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

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

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

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

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

___ (5) [Reserved]

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

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

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

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

___ (10) [Reserved]

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

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

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

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

___ (13) [Reserved]

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

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

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

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

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

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

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

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

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

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

- ___ (18) (i) 52.219-13, Notice of Set-Aside of Orders (MAR 2020) (15 U.S.C. 644(r)).
- ___ (ii) Alternate I (MAR 2020) of 52.219-13.
- ___ (19) 52.219-14, Limitations on Subcontracting (MAR 2020) (15 U.S.C. 637(a)(14)).
- ___ (20) 52.219-16, Liquidated Damages—Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).
- ___ (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (MAR 2020) (15 U.S.C. 657f).
- ___ (22) (i) 52.219-28, Post Award Small Business Program Rerepresentation (MAY 2020) (15 U.S.C. 632(a)(2)).
- ___ (ii) Alternate I (MAR 2020) of 52.219-28.
- ___ (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business (EDWOSB) Concerns (MAR 2020) (15 U.S.C. 637(m)).
- ___ (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (MAR 2020) (15 U.S.C. 637(m)).
- ___ (25) 52.219-32, Orders Issued Directly Under Small Business Reserves (MAR 2020) (15 U.S.C. 644(r)).
- ___ (26) 52.219-33, Nonmanufacturer Rule (MAR 2020) (15 U.S.C. 637(a)(17)).
- XX (27) 52.222-3, Convict Labor (JUN 2003) (E.O. 11755).
- xx(28) 52.222-19, Child Labor--Cooperation with Authorities and Remedies (JAN 2020) (E.O. 13126).
- XX (29) 52.222-21, Prohibition of Segregated Facilities (APR 2015).
- XX (30)(i) 52.222-26, Equal Opportunity (SEPT 2016) (E.O. 11246).
- ___ (ii) Alternate I (FEB 1999) of 52.222-26.
- XX (31)(i) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).
- ___ (ii) Alternate I (JUL 2014) of 52.222-35.
- XX (32)(i) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).
- ___ (ii) Alternate I (JUL 2014) of 52.222-36.
- XX (33) 52.222-37, Employment Reports on Veterans (JUN 2020) (38 U.S.C. 4212).
- XX (34) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496).
- XX (35)(i) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O. 13627).
- ___ (ii) Alternate I (MAR 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
- XX (36) 52.222-54, Employment Eligibility Verification (OCT 2015). (E. O. 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)

____ (37)(i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA-Designated Items (MAY 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

____ (53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (NOV 2007) (42 U.S.C. 5150

____ (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (NOV 2007) (42 U.S.C. 5150).

____ (55) 52.229-12, Tax on Certain Foreign Procurements (JUN 2020).

XX (56) 52.232-29, Terms for Financing of Purchases of Commercial Items (FEB 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

____ (57) 52.232-30, Installment Payments for Commercial Items (JAN 2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

____ (58) 52.232-33, Payment by Electronic Funds Transfer—System for Award Management (OCT 2018) (31 U.S.C. 3332).

____ (59) 52.232-34, Payment by Electronic Funds Transfer—Other than System for Award Management (JUL 2013) (31 U.S.C. 3332).

XX (60) 52.232-36, Payment by Third Party (MAY 2014) (31 U.S.C. 3332).

____ (61) 52.239-1, Privacy or Security Safeguards (AUG 1996) (5 U.S.C. 552a).

____ (62) 52.242-5, Payments to Small Business Subcontractors (JAN 2017)(15 U.S.C. 637(d)(13)).

____ (63)(i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (FEB 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).

____ (ii) Alternate I (APR 2003) of 52.247-64.

____ (iii) Alternate II (FEB 2006) of 52.247-64.

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

XX (1) 52.222-41, Service Contract Labor Standards (AUG 2018) (41 U.S.C. chapter 67).

XX (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (MAY 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

____ (3) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards--Price Adjustment (Multiple Year and Option Contracts) (AUG 2018) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

____ (4) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards--Price Adjustment (MAY 2014) (29 U.S.C 206 and 41 U.S.C. chapter 67).

____ (5) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (MAY 2014) (41 U.S.C. chapter 67).

_____ (6) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements (MAY 2014) (41 U.S.C. chapter 67).

xx(7) 52.222-55, Minimum Wages Under Executive Order 13658 (DEC 2015) (E.O. 13658).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- (viii) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).
- (ix) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).
- (x) 52.222-37, Employment Reports on Veterans (JUN 2020) (38 U.S.C. 4212).
- (xi) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.
- (xii) 52.222-41, Service Contract Labor Standards (Aug 2018), (41 U.S.C. chapter 67).
- (xiii) XX (A) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O. 13627).
 _____ (B) Alternate I (March 2, 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
- (xiv) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (May 2014) (41 U.S.C. chapter 67.)
- (xv) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements (May 2014) (41 U.S.C. chapter 67)
- (xvi) 52.222-54, Employment Eligibility Verification (Oct 2015) (E. O. 12989).
- (xvii) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015) (E.O. 13658).
- (xviii) [52.222-62](#), Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).
- (xix) (A) [52.224-3](#), Privacy Training (Jan 2017) ([5 U.S.C. 552a](#)).
- (B) Alternate I (Jan 2017) of [52.224-3](#).
- (xx) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
- (xxi) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations. (JUN 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.
- (xxii) 52.247-64, Preference for Privately-Owned U.S. Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.
- (2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.
- (End of clause)

The Contractor shall indicate acceptance of this letter contract by signing three copies of the contract and returning them to the Contracting Officer not later than _____. Upon acceptance by both parties, the Contractor shall proceed with performance of the work, including purchase of necessary materials.

(End of clause)

52.246-15 CERTIFICATE OF CONFORMANCE (APR 1984)

(a) When authorized in writing by the cognizant Contract Administration Office (CAO), the Contractor shall ship with a Certificate of Conformance any supplies for which the contract would otherwise require inspection at source. In no case shall the Government's right to inspect supplies under the inspection provisions of this contract be prejudiced. Shipments of such supplies will not be made under this contract until use of the Certificate of Conformance has been authorized in writing by the CAO, or inspection and acceptance have occurred.

(b) The Contractor's signed certificate shall be attached to or included on the top copy of the inspection or receiving report distributed to the payment office or attached to the CAO copy when contract administration (Block 10 of the DD Form 250) is performed by the Defense Contract Administration Services. In addition, a copy of the signed certificate shall also be attached to or entered on copies of the inspection or receiving report accompanying the shipment.

(c) The Government has the right to reject defective supplies or services within a reasonable time after delivery by written notification to the Contractor. The Contractor shall in such event promptly replace, correct, or repair the rejected supplies or services at the Contractor's expense.

(d) The certificate shall read as follows:

"I certify that on _____ [insert date], the _____ [insert Contractor's name] furnished the supplies or services called for by Contract No. _____ via _____ [Carrier] on _____ [identify the bill of lading or shipping document] in accordance with all applicable requirements. I further certify that the supplies or services are of the quality specified and conform in all respects with the contract requirements, including specifications, drawings, preservation, packaging, packing, marking requirements, and physical item identification (part number), and are in the quantity shown on this or on the attached acceptance document."

Date of Execution: _____

Signature: _____

Title: _____

(End of clause)

52.246-16 RESPONSIBILITY FOR SUPPLIES (APR 1984)

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

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

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

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

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

(d) Under paragraph (b) of this section, the Contractor shall not be liable for loss of or damage to supplies caused by the negligence of officers, agents, or employees of the Government acting within the scope of their employment.

(End of clause)

252.217-7027 CONTRACT DEFINITIZATION (DEC 2012)

(a) A **Undefinitized Contract Action (UCA)** is contemplated. The Contractor agrees to begin promptly negotiating with the Contracting Officer the terms of a definitive contract that will include (1) all clauses required by the Federal Acquisition Regulation (FAR) on the date of execution of the undefinitized contract action, (2) all clauses required by law on the date of execution of the definitive contract action, and (3) any other mutually agreeable clauses, terms, and conditions. The Contractor agrees to submit **firm fixed price** proposal and certified cost or pricing data supporting its proposal.

(b) The schedule for definitizing this contract is as follows (insert target date for definitization of the contract action and dates for submission of proposal, beginning of negotiations, and, if appropriate, submission of the make-or-buy and subcontracting plans and certified cost or pricing data).

Receipt of Qualifying Proposal:	9 September 2020
UCA Issued:	30 September 2020
Beginning of Negotiations:	30 November 2020
Complete Negotiations:	15 December 2020
Definitization of UCA:	19 February 2021

(c) If agreement on a definitive contract action to supersede this undefinitized contract action is not reached by the target date in paragraph (b) of this clause, or within any extension of it granted by the Contracting Officer, the Contracting Officer may, with the approval of the head of the contracting activity, determine a reasonable price or fee in accordance with subpart 15.4 and part 31 of the FAR, subject to Contractor appeal as provided in the Disputes clause. In any event, the Contractor shall proceed with completion of the contract, subject only to the Limitation of Government Liability clause.

(1) After the Contracting Officer's determination of price or fee, the contract shall be governed by--

(i) All clauses required by the FAR on the date of execution of this undefinitized contract action for either fixed-price or cost-reimbursement contracts, as determined by the Contracting Officer under this paragraph (c);

(ii) All clauses required by law as of the date of the Contracting Officer's determination; and

(iii) Any other clauses, terms, and conditions mutually agreed upon.

(2) To the extent consistent with paragraph (c)(1) of this clause, all clauses, terms, and conditions included in this

undefinitized contract action shall continue in effect, except those that by their nature apply only to an undefinitized contract action.

(d) The definitive contract resulting from this undefinitized contract action will include a negotiated **firm fixed price** in no event to exceed (b) (4)

(End of clause)

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):

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

(ii) For fixed price line items—

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

Receiving Report (DD 250) Destination Inspection / Destination Acceptance Inspection and Acceptance at place of destination

(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.

Invoice as 2-in-1 (FP Services Only – No DD250 Required)

(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.

[Note: The Contractor may use a WAWF “combo” document type to create some combinations of invoice and receiving report in one step.]

(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	(b) (4)
Issue By DoDAAC	(b) (4)
Admin DoDAAC**	(b) (4)
Inspect By DoDAAC	(b) (4)
Ship To Code	(b) (4)
Ship From Code	(b) (4)
Mark For Code	NA
Service Approver (DoDAAC)	NA
Service Acceptor (DoDAAC)	NA
Accept at Other DoDAAC	NA
LPO DoDAAC	NA
DCAA Auditor DoDAAC	NA
Other DoDAAC(s)	NA

(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.

"Not applicable."

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

(End of clause)

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

(a) Contract line item(s) 0001 is/are incrementally funded. For this/these item(s), 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 items(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 (b) (4) 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:

On execution of contract TBN

Upon Contract Definitization

(End of clause)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1 CONTRACT ID CODE	PAGE OF PAGES 1 36
2 AMENDMENT/MODIFICATION NO PZ0001	3 EFFECTIVE DATE 08-Jan-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) See Item 6		
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) ASTRAZENECA PHARMACEUTICALS LP (b) (6) 1800 CONCORD P KE WILMINGTON DE 19803-2902		9A. AMENDMENT OF SOLICITATION NO.		
		9B. DATED (SEE ITEM 11)		
		X 10A. MOD. OF CONTRACT/ORDER NO. W911QY20C0119		
CODE 36WK2		X 10B. DATED (SEE ITEM 13) 30-Sep-2020		
FACILITY CODE 36WK2				
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: FAR 52.216-25 Contract Definition				
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) Definition See Summary of Changes				
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) (b) (6)		
1 (b) (6)	15C. DATE SIGNED January 06, 2021	1 (b) (6) (Signature of Contracting Officer)	16C. DATE SIGNED 08-Jan-2021	

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1 CONTRACT ID CODE	PAGE OF PAGES 1 36	
2 AMENDMENT/MODIFICATION NO PZ0001	3 EFFECTIVE DATE 08-Jan-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) See Item 6			
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) ASTRAZENECA PHARMACEUTICALS LP (b) (6) 1800 CONCORD PIKE WILMINGTON DE 19803-2902			9A. AMENDMENT OF SOLICITATION NO.		
			9B. DATED (SEE ITEM 11)		
			X	10A. MOD. OF CONTRACT/ORDER NO. W911QY20C0119	
			X	10B. DATED (SEE ITEM 13) 30-Sep-2020	
CODE 36WK2	FACILITY CODE 36WK2				
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 CONTRACT 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: FAR 52.216-25 Contract Definition					
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) Definition See Summary of Changes					
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect					
15A. NAME AND TITLE OF SIGNER (Type or print)			16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) (b) (6) (b) (6)		
15B. CONTRACTOR/OFFEROR _____ (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY (b) (6) (Signature of Contracting Officer)		16C. DATE SIGNED 08-Jan-2021	

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:

SUMMARY OF CHANGES

ACTION OBLIGATION AMOUNT: (b) (4)

The purpose of this modification is to:

- 1) Definitize the contract by amending the value and funding of CLIN 0001 and add CLIN 0003 according to the negotiated prices.
- 2) Decrease the unit and total price of CLIN 0001.
- 3) Increase the funding on CLIN 0001.
- 4) Update the extended description in CLIN 0001.
- 5) Add CLIN 0003 Distribution and fully fund CLIN 0003.
- 6) Update the delivery date on CLIN 0001 to match the SOW required delivery of (b) (4).
- 7) Update the SOW and Section F in order for this contract to align with the OTA.
- 8) Updated by substitution Sections F, G & H.
- 9) Remove clauses.

SECTION SF 1449 - CONTINUATION SHEET

SOLICITATION/CONTRACT FORM

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

SUPPLIES OR SERVICES AND PRICES

CLIN 0001

A definitized action has occurred in this modification

The CLIN extended description has changed from:

The contractor shall provide SARS-CoV-2 therapeutic AZD7442 (b) (4) All required work shall be IAW the SOW and Commercial Solution Proposal titled "AZD7442 JPEO CSO Technical Volume_revised 09Sep", dated September 9, 2020.

To:

The contractor shall provide SARS-CoV-2 therapeutic AZD7442 (b) (4) All required work shall be IAW the SOW and Commercial Solution Proposal titled "AZD7442 JPEO CSO Technical Volume_revised 09Sep", dated November 16, 2020.

The unit price amount has decreased by (b) (4) from (b) (4) .

The total cost of this line item has decreased by (b) (4) .

CLIN 0002

A definitized action has occurred in this modification

The pricing detail quantity (b) (4) has been added.

The unit of issue Each has been added.

SUBCLIN 000102 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000102	ACRN AA @ (b) (4) FFP PURCHASE REQUEST NUMBER: 0011555540-0001				\$0.00

NET AMT \$0.00

ACRN AA (b) (4)
CIN: GFEB001155554000002

CLIN 0003 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003	SARS-CoV-2 Therapeutic Distribution FFP The contractor shall provide distribution for SARS-CoV-2 therapeutic AZD7442 (b) (4) (b) (4). All required work shall be IAW the SOW and Commercial Solution Proposal titled "AZD7442 JPEO CSO Technical Volume_revised 09Sep", dated November 16, 2020. FOB: Destination PSC CD: 6550	1	Each	(b) (4)	(b) (4)

NET AMT (b) (4)

SUBCLIN 000301 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000301	ACRN AA @ (b) (4) FFP PURCHASE REQUEST NUMBER: 0011555540-0001				\$0.00

NET AMT \$0.00

ACRN AA (b) (4)
CIN: GFEB001155554000003

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).

SUBCLIN 000102:
Funding on SUBCLIN 000102 is initiated as follows:

ACRN: AA

CIN: GFEB001155554000002

Acctng Data: 09720202021013000018170552520252 S.0074658.1.1.15 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: AHPDD

SUBCLIN 000301:
Funding on SUBCLIN 000301 is initiated as follows:

ACRN: AA

CIN: GFEB001155554000003

Acctng Data: 09720202021013000018170552520252 S.0074658.1.1.15 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: AHPDD

DELIVERIES AND PERFORMANCE

The following Delivery Schedule item for CLIN 0001 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
(b) (4)	100,000	JPEO-CBRND (b) (6) 8222 HOADLEY RD E5101 ABERDEEN PROVING GROUND MD 21010 (b) (6) FOB: Destination	W90ZQ2

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
(b) (4)	100,000	JPEO-CBRND (b) (6) 8222 HOADLEY RD E5101 ABERDEEN PROVING GROUND MD 21010 (b) (6) FOB: Destination	W90ZQ2

The following Delivery Schedule for CLIN 0003 has been added:

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

(b) (4)

1

JPEO-CBRND

W90ZQ2

(b) (6)

8222 HOADLEY RD E5101

ABERDEEN PROVING GROUND MD 21010

(b) (6)

FOB: Destination

INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000102:

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

The following Acceptance/Inspection Schedule was added for CLIN 0003:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 000301:

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

The following have been modified:

ADDITIONAL SHIPPING INFO

SECTION F DELIVERIES OR PERFORMANCE

F.1. The distribution plan is currently TBD. (b) (4)

(b) (4)

The first 100,000 doses to be procured under this agreement (b) (4)

(b) (4)

F.2. **Product Development Source Material and Manufacturing Reports and Projections:** The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and location and nature of non-clinical and clinical study sites.

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

- Contractor will submit Product Development Source Material Report
 - Within month of contract award
 - Within 30 days of substantive changes are made to sources and/or materials
 - and on the 6th month contract anniversary.
- Contractor will update the Dose Tracking Template weekly, during manufacturing campaigns and COVID response, with the first deliverable submission within 15 days of award/modification
- The Government will provide written comments to the Product Development Source Material and

Manufacturing Report within 15 business days after the submission

- If corrective action is recommended, Contractor must address all concerns raised by the Government in writing

F.3. Contractor Locations: The contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors.

Contractor will submit Work Locations Report:

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

F.4. Access and General Protection/Security Policy and Procedures: This standard language text is applicable to ALL employees working on critical information related to Operation Warp Speed (OWS) within an area of performance within a Government controlled installation, facility or area. Employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The performer also shall provide all information required for background checks necessary to access critical information related to OWS, and to meet Government installation access requirements to be accomplished by installation Director of Emergency Services or Security Office. The workforce must comply with all personnel identity verification requirements as directed by the Government and/or local policy. In addition to the changes otherwise authorized by the changes clause of this agreement, should the

security status of OWS change the Government may require changes in performer security matters or processes. In addition to the industry standards for employment background checks, The Contractor must be willing to have key individuals, in exceptionally sensitive positions, identified for additional vetting by the United States Government.

CONTRACT ADMINISTRATION

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.

Contracting Officer:

(b) (6)

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

Procurement Specialist:

(b) (6)

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

G.2 Government Technical Points of Contact: Program Manager:

(b) (6)

G.3 Contractor's Contract Administration

Technical Point of Contact:

Primary Investigator

(b) (6)
[Redacted]
[Redacted]
[Redacted]

Administrative Point of Contact:

(b) (6)
[Redacted]
[Redacted]
[Redacted]

G.4 Contractor's Past Performance Point of Contact (POC): Annual contract past performance evaluations will be performed by the government. The offeror shall identify a Point of Contact (POC) to participate in these on-line evaluations. This individual is required to register in the Contractor Performance Assessment Reporting System (CPARS @ <http://www.cpars.csd.disa.mil>) and respond to the government evaluations in a timely manner. The contractor POC responsible for this action is:

(b) (6)
[Redacted]
[Redacted]
[Redacted]

G.5 Notifications of Revisions and Changes: 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.

STATEMENT OF WORK

ADDENDUM: The following pages hereby supplements FAR 52.212-4

1. Background:

In December 2019, a novel (new) coronavirus known as SARS-CoV-2 ("the virus") 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 Services (HHS) 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.

Under the President's Operation Warp Speed Mission, HHS is leading a whole of nation effort with the primary goal to execute on a well-defined portfolio of COVID-19 Medical Countermeasures (MCM) candidates to maximize probability of having safe and effective diagnostics, therapeutics and vaccines as fast as possible for mass distribution. As such, BARDA has an Area of Interest (AoI) for therapeutics manufacturing and fill-finish of advanced SARS-CoV-2 MCMs. Therapeutics manufacturing is expected to meet the necessary US Food and Drug Administration (FDA) requirements for beginning a Phase 3 clinical trial, and the product be granted licensure by the FDA.

2. Objective:

The government seeks to acquire courses of therapeutic MCMs against SARS-CoV-2 that are either direct acting antivirals or host directed therapeutics, which indirectly inhibit the coronavirus lifecycle. Manufacturing

shall occur using Current Good Manufacturing Practices (cGMP) validated manufacturing processes for bulk drug substance and fill and finished drug product. The specific objective is the acquisition of a minimum of 100,000 (b) (4) dose courses for a targeted US population by (b) (4), to treat the US population indicated in the Offeror's target population. The intent is "Large Scale production capability in a short period of time with little to no advance notice under the conditions for which the MCM is required."

Candidate MCM therapeutics shall have at minimum, capability of obtaining Emergency Use Authorization (EUA) and/or a reasonable chance of moving to Phase 3 clinical trials by (b) (4) including all development plans and efforts, manufacturing, all done in support of the goal of achieving FDA approval/licensure in (b) (4). Offerors must have started, or have completed, a Phase 1 clinical study no later than (b) (4).

3. Tasks:

Task 1: Establish a quality agreement between the US Government and Offeror on requirements for the US Government to accept packaged drug product as a completed deliverable. Quality agreement must be negotiated within the first (b) (4) of award and prior to Government acceptance of drug product.

Task 2: Provide within (b) (4) of award Product Development Source Material and Manufacturing Plan to fulfill the US Government order. The manufacturing plan should include all materials required for drug substance/active pharmaceutical ingredient manufacturing and finished drug product, an acquisition plan for acquiring necessary materials, all key subcontractors and manufacturing sites, and a detailed schedule for providing the final product to the US Government.

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

Task 4 – Storage

(b) (4)

Task 5 – Distribution

(b) (4)

Task 6 – Program Management Activities:

The offeror must establish the capacity in compliance with FDA cGMP regulations, and Biosafety Level standards if applicable. The offeror must be responsible for management of all activities, subcontractors, etc. to meet the goals of the contract, including holding routine meetings with USG, and completion of meeting minutes. On a monthly basis, the offeror(s) must provide a monthly report that includes capacity availability and utilization, as well as any issues that affect the operational availability of the reserved capacity.

4. Deliverables:


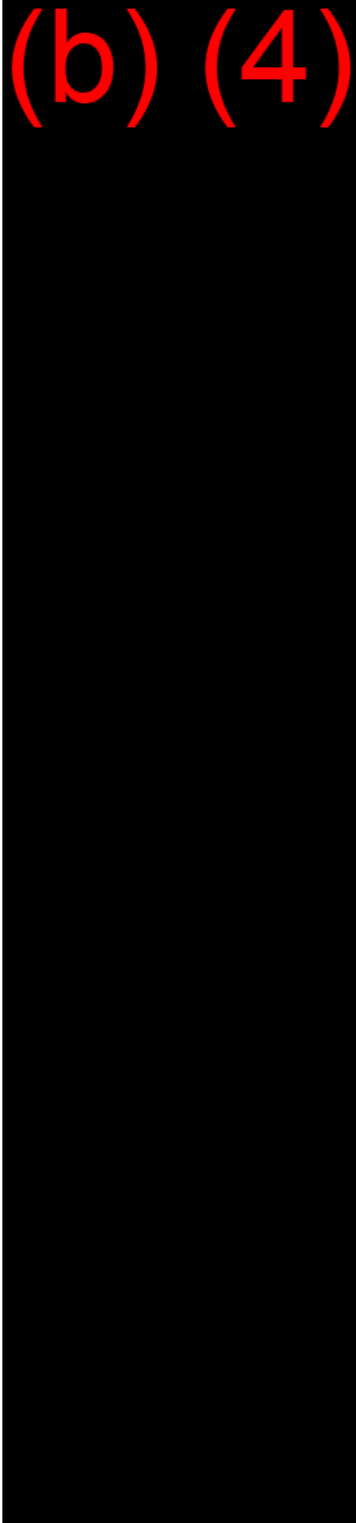
CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
01	Meetings			

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
01.1	Post Award Teleconference	<p>The Contractor shall complete an initial teleconference after agreement award</p> <ol style="list-style-type: none"> 1. Outline activities for the next 30 days 2. Discuss agenda items for the post-award Kickoff Meeting (01.2) 	<ul style="list-style-type: none"> •Within one week of Agreement award •Contractor shall provide agenda and establish a teleconference number at least 3 business days in advance of the teleconference unless notified that BARDA will supply one •PM edits/approves and instructs Contractor to distribute agenda prior to meeting by at least 2 business days •Contractor provides meeting minutes to PM within 3 business days after the meeting •PM reviews, comments and approves minutes within 10 business days 	(b) (4)
01.2	Kickoff Meeting	<p>The Contractor shall complete a Kickoff meeting after agreement award</p>	<ul style="list-style-type: none"> •Within a month of agreement award, pending concurrence by the agreements officer •Contractor shall provide itinerary and agenda at least 5 business days in advance of site visit or virtual meeting •PM edits/approves and instructs Contractor to distribute agenda prior to meeting by at least 3 business days •Contractor provides meeting minutes to PM within 3 business days after the meeting •PM reviews, comments, and approves minutes within 10 business days 	
01.3	Every 2 weeks Teleconference	<p>The Contractor shall participate in teleconferences every 2 weeks, with BARDA to discuss the performance on the Agreement. Meeting frequency can be increased as needed during the course of the project</p>	<ul style="list-style-type: none"> •Contractor provides agenda to PM no later than 2 business days in advance of meeting •PM edits/approves and instructs Contractor to distribute agenda prior to meeting •Contractor distributes agenda and presentation materials at least 24 hours in advance •Contractor provides meeting minutes to PM 	

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
			<p>within 3 business days of the meeting</p> <ul style="list-style-type: none"> •PM reviews, comments, and approves minutes within 6 business days •Updates to include: BARDA Contractor Clinical Trials Information Sheet, forecast of activities across each WBS number as well as updates on planned regulatory submissions. 	(b) (4)
01.5	FDA Meeting Minutes and other communications with FDA	As described in Article 13	<ul style="list-style-type: none"> •Contractor shall notify BARDA of upcoming FDA meeting within PM of scheduling Type A, B or C meetings OR within (b) (4) of meeting occurrence for ad hoc meetings •The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to BARDA within PM of receipt 	
02	Technical Reporting			
02.3 (Draft) 02.4 (Final)	Draft and Final Technical Progress Report	A draft Final Technical Progress Report containing a summation of the work performed and the results obtained over the entire Agreement. This report shall be in sufficient detail to fully describe the progress achieved under all milestones. Report should contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained during the Agreement. Descriptions and rationale for activities and milestones that were not completed as planned should be provided. The draft	<ul style="list-style-type: none"> •The Draft Technical Progress Report shall be submitted (b) (4) before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP •PM will provide feedback on draft report within 15 calendar days of receipt, which the Contractor shall consider incorporating into the Final Report •The Final Technical report will include all milestone reports submitted throughout the period of performance and include an overarching executive summary. 	(b) (4)

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
		<p>report shall be duly marked as 'Draft'</p> <p>The Final Technical Progress Report incorporating feedback received from BARDA and containing a summation of the work performed and the results obtained for the entire agreement PoP. The final report shall document the results of the entire Agreement. The final report shall be duly marked as 'Final'. A cover letter with the report will contain a summary (not to exceed 200 words) of salient results achieved during the performance of the Agreement</p>		(b) (4)
02.6	Product Development Source Material and Manufacturing Reports and Projections	<p>The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and location and nature of non-clinical and clinical study sites.</p> <p>The Contractor will provide manufacturing reports and manufacturing dose tracking projections/actuals utilizing the "COVID-</p>	<ul style="list-style-type: none"> • Contractor will submit Product Development Source Material Report <ul style="list-style-type: none"> ○ Within month of Agreement award ○ Within 30 days of substantive changes are made to sources and/or materials ○ Or on the 6th month contract anniversary. • Contractor will update the Dose Tracking Template weekly during manufacturing campaigns and daily during response operations (where a Public Health Emergency has been declared) and COVID-19 response, with the first deliverable submission within 15 days of award/modification. Updates to be provided weekly in advance of commercial-scale manufacturing and daily once material for use in response operations 	

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
		19 Dose Tracking Templates” or similar, on any contract/agreement that is manufacturing product, including product for clinical trial use.	<p>begins manufacture.</p> <ul style="list-style-type: none"> • The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission • If corrective action is recommended, Contractor must address all concerns raised by BARDA in writing • Product Development and Source Material report to be submitted via spreadsheet; Dose Tracking can be completed via spreadsheet or other format (e.g. XML or JSON) as agreed to by USG and company. 	(b) (4)
02.7	Contractor Locations	The Contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-Contractors.	<p>Contractor will submit Work Locations Report:</p> <ul style="list-style-type: none"> • Within (b) (4) of Agreement award • Within (b) (4) after a substantive location or capabilities change • Within (b) (4) of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO 	
2.8	Pandemic Management Plan	A pandemic facility and/or operational management plan including change procedures from normal to pandemic operations Contractor will prepare an operational plan to continue operations in the event of a declared pandemic emergency.	<p>Contractor will submit Pandemic Management Plan:</p> <ul style="list-style-type: none"> • Draft within (b) (4) of award • Final within (b) (4) of award 	

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
02.11	Supply Chain and Distribution Tracking	<p>Distribution Concept of Operations. BARDA, and MCM Manufacturers play an important role in the distribution of therapeutics to the American people under a nationwide response. BARDA will work with the manufacturer to monitor what is in the manufacturing pipeline using the enclosed dose tracking templates (see above). Contractor will relay final drug product information as it is being released to the BARDA/ASPR for allocation and ordering by state public health departments. (b) (4)</p> 	<p>Provide the following information in order to coordinate the movement and delivery of AZD7442</p> 	<p>(b) (4)</p>

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
			(b) (4)(b) (4)	
02.11a	Distribution Plan	<p>(b) (4)</p> <p>The plan shall comply with applicable provisions of the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov 27, 2013), taking into account FDA's regular guidance for the COVID-19 public health response.</p>	<ul style="list-style-type: none"> • (b) (4) 	
02.12	Manufacturing Development Plan	<p>This plan shall describe("describe the manufacturing process for the drug/biologic product to ensure conformity with §501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21</p>	<ul style="list-style-type: none"> • Plan will be delivered electronically (b) (4) of Agreement award to the KO and PM 	

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
		<p>United States Code (USC) §351 (a)(2)(B)), regarding good manufacturing practices (GMP)), but is not limited to planned or completed drug substance studies; list of excipients and information to support the safety of excipients that, when appropriate, shall be cross-referenced; drug product and formulation development summary from initial concept through final design; physicochemical and biological properties; manufacturing process development and validation program documents; container closure system documents [description, choice, rationale]; microbiological attributes documents and plans; compatibility documents (e.g., precipitation); assay development and validation, stability plan; and any associated risks.")</p>		(b) (4)
02.13	Quality Management Plan	<p>Plan may include, but is not limited to the quality policy and objectives, management review, competencies and training, process document control, feedback, evaluation, corrective action and preventive action, process improvement, measurement, and data analysis processes. The framework is normally divided into infrastructure, senior</p>	<ul style="list-style-type: none"> Plan will be delivered electronically (b) (4) of Agreement award to the KO and PM 	

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
		management responsibility, resource management, lifecycle management, and quality management system evaluation		(b) (4)
02.14	Quality Agreement	Agreement will determine the conditions of acceptance by the USG of the purchased product. No product will be accepted by the USG until a quality agreement is in place.	<ul style="list-style-type: none"> Agreement will be signed by the USG and the manufacturer (b) (4) of Agreement award Agreement will be delivered electronically to the KO and PM 	
2.15	Release documentation for doses to be delivered	(b) (4)	<ul style="list-style-type: none"> (b) (4) 	
2.16	Security Plan	As described in Article 5.B(11)	<ul style="list-style-type: none"> Within (b) (4) of award/definitization 	
03	Audits			
03.2	FDA Inspections	In the event of an FDA inspection that occurs in relation to this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the PM and KO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also	<ul style="list-style-type: none"> Contractor shall notify KO and PM (b) (4) of a scheduled FDA audit or within (b) (4) of an ad hoc site visit/audit if the FDA does not provide advanced notice Contractor shall provide copies of any FDA audit report received from subContractors that occur as a result of this contract or for this product within (b) (4) of receiving correspondence from the FDA or third party Within (b) (4) of audit report, Contractor shall provide KO with a plan for addressing areas of nonconformance, if any are identified 	

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
		provide copies of any FDA audits received from subContractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector		(b) (4)
03.3	QA Audits	BARDA reserves the right to participate in QA audits performed by the Contractor. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subContractor. If action is requested of the subContractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subContractors to address these concerns and plans for corrective action	<ul style="list-style-type: none"> • Contractor shall notify KO and PM a minimum of (b) (4) in advance of upcoming, audits/site visits of subContractors • Contractor shall notify the PM and KO (b) (4) of report completion. • PM and KO will review the report and provide a response to the Contractor with (b) (4) 	
03.4	Risk Management Plan (RMP)	The Contractor shall provide an RMP that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost,	<ul style="list-style-type: none"> • A Draft is due (b) (4) within contract award; updates to the RMP are due concurrent with Monthly Technical Progress Reports. The Contractor may choose to notify the government up to two times every three months if there are no changes from the prior submission, and not submit an update • BARDA will provide Contractor with a list of 	

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
		schedule and performance	<p>concerns in response plan submitted</p> <ul style="list-style-type: none"> Contractor must address, in writing, all concerns raised by BARDA within (b) (4) of Contractor's receipt of BARDA's concerns 	(b) (4)
03.5	Integrated Master Schedule (IMS)	<p>The Contractor shall provide an IMS that illustrates project tasks, dependencies, durations throughout the period of performance, and milestones (GO/NO-GO). The IMS must map to the WBS, and provide baseline, and actual or forecast dates for completion of tasks</p>	<ul style="list-style-type: none"> The IMS is to be submitted in both PDF and Microsoft Project Form to the PM The first Draft of the IMS is due (b) (4) within contract award The Government will request revisions (b) (4) at which point the schedule baseline for the period of performance will be set Thereafter an updated IMS is due concurrent with Monthly Technical Progress Reports During a declared Public Health Emergency, the IMS is to be delivered (b) (4) of contract award, updates are due (b) (4) and any significant change (b) (4) must be reported immediately to the PM and/or designee. 	(b) (4)
03.6	Deviation Notification and Mitigation Strategy	<p>Process for changing IMS activities associated with cost and schedule as baselined. Contractor shall notify BARDA of significant proposed changes the IMS defined as (b) (4) which would require a PoP extension. Contractor shall provide a high level management strategy for risk mitigation</p>	<ul style="list-style-type: none"> Due at least (b) (4) prior to the Contractor anticipating the need to implement changes 	(b) (4)

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
03.7	Incident Report	<p>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.</p> <p>(b) (4)</p> <p>but should be confirmed in consultation with the PM. Incidents that present liability to the project even without cost/schedule impact, such as breach of GCP during a clinical study, must also be reported</p>	<ul style="list-style-type: none"> •Due within (b) (4) of activity or incident or within (b) (4) for a security activity or incident •Email or telephone with written follow-up to PM and KO •Additional updates due to PM and KO within (b) (4) of additional developments •Contractor shall submit within (b) (4) a Corrective Action Plan (if deemed necessary by either party) to address any potential issues •If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by BARDA within (b) (4) of receiving such concerns 	(b) (4)
09	Advanced R&D Products			
09.1	Technical Documents	<p>Upon request, Contractor shall provide KO and PM with deliverables from the following contract funded activities: quality agreements between Contractors and sub-Contractors, process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The KO and PM reserve the right to request within the PoP a non-proprietary technical document for distribution within the Government</p>	<ul style="list-style-type: none"> •Contractor shall provide technical document within (b) (4) of KO or PM request. Contractor can request additional time on an as needed basis •If corrective action is recommended, the Contractor must address, in writing, concerns raised by BARDA in writing 	(b) (4)

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
09.2	Publications	Any manuscript or scientific meeting abstract describing manufacturing of product and containing data generated under this contract must be submitted to BARDA for review prior to submission. Acknowledgment of BARDA funding must be included as noted in contract articles H.5 and H.6	<ul style="list-style-type: none"> Contractor must submit all manuscript or scientific meeting abstract to PO and KO prior to submission/presentation by (b) (4) for manuscripts and (b) (4) for abstracts or posters Contractor must address in writing all concerns raised by JPEO in writing Final submissions shall be submitted to JPEO (b) (4) of its submission 	(b) (4)
10	Regulatory Documents			
10.1	FDA Correspondence	As described in Article 13	<ul style="list-style-type: none"> Contractor shall provide copies of any FDA correspondence within (b) (4) of correspondence 	
10.3	EUA Filing	The Contractor shall provide a copy of any request for EUA submitted to the FDA	<ul style="list-style-type: none"> Within (b) (4) after submission to the FDA 	
10.4	BLA Filing	The Contractor shall provide a copy of the BLA submitted to the FDA	<ul style="list-style-type: none"> Within (b) (4) after submission to the FDA 	
11	Press Releases	Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases	<ul style="list-style-type: none"> Contractor shall ensure that the KO has received and approved an advanced copy of any press release to this contract not less than (b) (4) prior to the issuance of the press release If corrective action is required, the Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases Any final press releases shall be submitted to BARDA no later than (b) (4) prior to its release 	

* The Government acknowledges that deliverables identified with an asterisk (“*”) in the table above will require AstraZeneca to deliver to the Government certain proprietary and confidential trade secret information related to manufacturing, purification and formulation process for the monoclonal antibody drug product (AZD7422). (b) (4)

(b) (4)

[Redacted]

(b) (4)

5. Detailed Description of Select Contract Deliverables

Supremacy Clause: In the event of any conflict or inconsistency between the narrative descriptions provided in this Section and the Table above, the Table shall govern.

1. Operational Security (OPSEC) Plan

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

2. Security Plan

The Awardee shall develop a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the Government requirement. This plan shall establish security practices and procedures that demonstrate how the Awardee will meet and adhere to the security requirements outlined below prior to the commencement of product manufacturing, and shall be delivered to the Government within thirty (30) calendar days of award. (b) (4)

[Redacted]

The Government will review in detail and submit comments within ten (10) business days to the Contracting Officer (KO) to be forwarded to the Awardee. The Awardee shall review the Draft Security Plan comments, and, submit a Final Security Plan to the U.S. Government within thirty (30) calendar days after receipt of the comments.

The Security Plan shall include a timeline for compliance of all the required security measures outlined by the Government.

Upon completion of initiating all security measures, the Awardee shall supply to the Agreements Officer a letter certifying compliance to the elements outlined in the Final Security Plan.

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

Government Security Requirements:

1. Facility Security Plan

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

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

Protective Security Forces	Requirements for security officers will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces Operations	<ul style="list-style-type: none"> a) Must have in-service training program. b) Must have Use of Force Continuum. c) Must have communication systems available (i.e., landline on post, cell phones, handheld radio, and desktop computer). d) Must have Standing Post Orders. e) Must wear distinct uniform identifying them as security officers.
5. Security Operations	
Description:	
Information Sharing	<ul style="list-style-type: none"> a) Establish formal liaison with law enforcement. b) Meet in person at a minimum annually. Document meeting notes and keep them on file for a, minimum of 12 months. POC information for LE Officer that attended the meeting must be documented. c) Implement procedures for receiving and disseminating threat information.
Training	<ul style="list-style-type: none"> a) Conduct new employee security awareness training. b) Conduct and maintain records of annual security awareness training.
Security Management	<ul style="list-style-type: none"> a) Designate a knowledgeable security professional to manage the security of the facility. b) Ensure subcontractor compliance with all Government security requirements.
6. Personnel Security	
Description:	
Records Checks	Verification of social security number, date of birth, citizenship, education credentials, five-year previous employment history, five-year previous residence history, FDA disbarment, sex offender registry, credit check based upon position within the company; motor vehicle records check as appropriate; and local/national criminal history search.
Hiring and Retention Standards	<ul style="list-style-type: none"> a) Detailed policies and procedures concerning hiring and retention of employees, employee conduct, and off boarding procedures. b) Off Boarding procedures should be accomplished within 24 hour of employee leaving the company. This includes termination of all network access.
7. Information Security	
Description:	
Physical Document Control	<ul style="list-style-type: none"> a) Applicable documents shall be identified and marked as procurement sensitive, proprietary, or with appropriate government markings. b) Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet/desk or other storage device and not be left unattended. c) Access to sensitive information should be restricted to those with a need to know.
Document Destruction	Documents must be destroyed using approved destruction measures (i.e., shredders/approved third party vendors / pulverizing / incinerating).
8. Information Technology & Cybersecurity	
Description:	
Identity Management	<ul style="list-style-type: none"> a) Physical devices and systems within the organization are inventoried and accounted for annually. b) Organizational cybersecurity policy is established and communicated. c) Asset vulnerabilities are identified and documented. d) Cyber threat intelligence is received from information sharing forums and sources. e) Threats, vulnerabilities, likelihoods, and impacts are used to determine risk. f) Identities and credentials are issued, managed, verified, revoked, and audited for authorized devices, users and processes. g) Users, devices, and other assets are authenticated (e.g., single-factor, multifactor) commensurate with the risk of the transaction (e.g., individuals' security and privacy risks and other organizational risks)
Access Control	<ul style="list-style-type: none"> a) Limit information system access to authorized users. b) Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access. c) Limit physical access to information systems, equipment, and server rooms with electronic access controls. d) Limit access to/ verify access to use of external information systems.

Training	a) Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.
Audit and Accountability	a) Create, protect, and retain information system audit records to the extent needed to enable the monitoring, analysis, investigation, and reporting of unlawful, unauthorized, or inappropriate system activity. Records must be kept for minimum must be kept for 12 months. b) Ensure the actions of individual information system users can be uniquely traced to those users. c) Update malicious code mechanisms when new releases are available. d) Perform periodic scans of the information system and real time scans of files from external sources as files are downloaded, opened, or executed.
Configuration Management	a) Establish and enforce security configuration settings. b) Implement sub networks for publically accessible system components that are physically or logically separated from internal networks.
Contingency Planning	a) Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times.
Incident Response	a) Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery of cybersecurity incidents. Exercise this capability annually.
Media and Information Protection	a) Protect information system media, both paper and digital. b) Limit access to information on information systems media to authorized users. c) Sanitize and destroy media no longer in use. d) Control the use of removable media through technology or policy.
Physical and Environmental Protection	a) Limit access to information systems, equipment, and the respective operating environments to authorized individuals. b) Intrusion detection and prevention system employed on IT networks. c) Protect the physical and support infrastructure for all information systems. d) Protect information systems against environmental hazards. e) Escort visitors and monitor visitor activity.
Network Protection	Employ intrusion prevention and detection technology with immediate analysis capabilities.
9. Transportation Security	
Description: Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage.	
Drivers	a) Drivers must be vetted in accordance with Government Personnel Security Requirements. b) Drivers must be trained on specific security and emergency procedures. c) Drivers must be equipped with backup communications. d) Driver identity must be 100 percent confirmed before the pick-up of any Government product. e) Drivers must never leave Government products unattended, and two drivers may be required for longer transport routes or critical products during times of emergency. f) Truck pickup and deliveries must be logged and kept on record for a minimum of 12 months.
Transport Routes	a) Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency. b) Transport routes should be continuously evaluated based upon new threats, significant planned events, weather, and other situations that may delay or disrupt transport.
Product Security	a) Government products must be secured with tamper resistant seals during transport, and the transport trailer must be locked and sealed. <ul style="list-style-type: none"> • Tamper resistant seals must be verified as "secure" after the product is placed in the transport vehicle. b) Government products should be continually monitored by GPS technology while in transport, and any deviations from planned routes should be investigated and documented.

	c) Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.
10. Security Reporting Requirements	
Description: The partner facility shall notify the Government Security Team within 24 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of government products. The facts and circumstances associated with these incidents will be documented in writing for government review.	
11. Security Audits	
Description: The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and subcontractor.	

TERMS AND CONDITIONS

SPECIAL CONTRACT REQUIREMENTS

H.1. The government hereby issues this contract action as a definitized contract action for the manufacturing therapeutic AZD7442 in support of OWS. The award is being executed as a result of the MCM Commercial Solutions Opening (CSO) Solicitation W911QY-20-S-C001 Area of Interest (AOI) Number A003: SARS-CoV-2 Medical Counter Measures (MCM) Therapeutics.

H.2. 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 contractors 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:

Technical point of contact:

Primary Investigator

(b) (6)

(b) (6)

Administrative point of contact:

(b) (6)

(b) (6)

H.3. 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 guidance. 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.

The contractor further agrees to include the substance of this language in any subcontract, which may be awarded under this contract.

H.4. Contractor's Organization: The contractor's organization shall be established with authority to effectively accomplish the objectives of the Statement of Work. This organization shall become effective upon award of the contract and its integrity shall be maintained for the duration of the contract effort.

H.5. 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 which specifically relates to AZD7442 (i.e., would not apply more broadly to AstraZeneca's other antibody programs, such as its manufacturing platform), except authorized by government personnel or upon written approval of the CO 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 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.

H.6. 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, and the Government's consent shall not be unreasonably withheld or delayed (b) (4)

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 government logos 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 government approval or endorsement of the product(s) or service(s) provided.

d. The contractor shall include this language, 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 government 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 by the U.S. government under Contract No. "W911QY-20-C- 0119".

The US government is authorized to reproduce and distribute reprints for governmental purposes notwithstanding any copyright notation thereon.

H.7. Confidentiality of Information:

a. Confidential information, as used in this article, means 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.

h. Awardee shall include the requirements set forth in this Article in all Sub-awards entered into after the date of effectiveness of this Agreement. Awardee acknowledges that confidential information will not be provided to sub-agreement holders unless or until Article H.7 flows down to the relevant sub-agreement, and such entity agrees to be in substantial compliance with this Article H.7.

H.8. Subcontracts:


a. The Government acknowledges that, in order to combat the global pandemic and launch AZD7442 as quickly as possible, (b) (4)

[REDACTED]

b. For clarity, as detailed within the Articles themselves, the following Articles require flow-down to subagreements/contracts (b) (4)

[REDACTED]

[REDACTED]

H.9 Taxes: (b) (4)
**H.10 Title and Risk of Loss: (b) (4)**
**52.212-5 CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS--COMMERCIAL ITEMS (AUG 2020)**

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

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

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

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

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

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

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

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

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

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

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

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

___ (5) [Reserved]

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

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

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

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

___ (10) [Reserved]

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

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

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

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

___ (13) [Reserved]

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

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

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

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

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

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

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

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

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

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

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

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

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

____ (20) 52.219-16, Liquidated Damages—Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).

____ (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (MAR 2020) (15 U.S.C. 657f).

____ (22) (i) 52.219-28, Post Award Small Business Program Rerepresentation (MAY 2020) (15 U.S.C. 632(a)(2)).

____ (ii) Alternate I (MAR 2020) of 52.219-28.

____ (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business (EDWOSB) Concerns (MAR 2020) (15 U.S.C. 637(m)).

____ (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (MAR 2020) (15 U.S.C. 637(m)).

____ (25) 52.219-32, Orders Issued Directly Under Small Business Reserves (MAR 2020) (15 U.S.C. 644(r)).

____ (26) 52.219-33, Nonmanufacturer Rule (MAR 2020) (15 U.S.C. 637(a)(17)).

XX (27) 52.222-3, Convict Labor (JUN 2003) (E.O. 11755).

XX(28) 52.222-19, Child Labor--Cooperation with Authorities and Remedies (JAN 2020) (E.O. 13126).

XX (29) 52.222-21, Prohibition of Segregated Facilities (APR 2015).

XX (30)(i) 52.222-26, Equal Opportunity (SEPT 2016) (E.O. 11246).

____ (ii) Alternate I (FEB 1999) of 52.222-26.

XX (31)(i) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).

____ (ii) Alternate I (JUL 2014) of 52.222-35.

XX (32)(i) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).

____ (ii) Alternate I (JUL 2014) of 52.222-36.

XX (33) 52.222-37, Employment Reports on Veterans (JUN 2020) (38 U.S.C. 4212).

XX (34) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496).

XX (35)(i) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O. 13627).

____ (ii) Alternate I (MAR 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).

(36) 52.222-54, Employment Eligibility Verification (OCT 2015). (E. O. 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)

____ (37)(i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA–Designated Items (MAY 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

____ (53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (NOV 2007) (42 U.S.C. 5150

____ (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (NOV 2007) (42 U.S.C. 5150).

____ (55) 52.229-12, Tax on Certain Foreign Procurements (JUN 2020).

XX (56) 52.232-29, Terms for Financing of Purchases of Commercial Items (FEB 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

____ (57) 52.232-30, Installment Payments for Commercial Items (JAN 2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

____ (58) 52.232-33, Payment by Electronic Funds Transfer—System for Award Management (OCT 2018) (31 U.S.C. 3332).

____ (59) 52.232-34, Payment by Electronic Funds Transfer—Other than System for Award Management (JUL 2013) (31 U.S.C. 3332).

(60) 52.232-36, Payment by Third Party (MAY 2014) (31 U.S.C. 3332).

____ (61) 52.239-1, Privacy or Security Safeguards (AUG 1996) (5 U.S.C. 552a).

____ (62) 52.242-5, Payments to Small Business Subcontractors (JAN 2017)(15 U.S.C. 637(d)(13)).

____ (63)(i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (FEB 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).

____ (ii) Alternate I (APR 2003) of 52.247-64.

____ (iii) Alternate II (FEB 2006) of 52.247-64.

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

(1) 52.222-41, Service Contract Labor Standards (AUG 2018) (41 U.S.C. chapter 67).

(2) 52.222-42, Statement of Equivalent Rates for Federal Hires (MAY 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

____ (3) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards--Price Adjustment (Multiple Year and Option Contracts) (AUG 2018) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

____ (4) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards--Price Adjustment (MAY 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

____ (5) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (MAY 2014) (41 U.S.C. chapter 67).

____ (6) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements (MAY 2014) (41 U.S.C. chapter 67).

(7) 52.222-55, Minimum Wages Under Executive Order 13658 (DEC 2015) (E.O. 13658).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(x) 52.222-37, Employment Reports on Veterans (JUN 2020) (38 U.S.C. 4212).

(xi) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.

(xii) 52.222-41, Service Contract Labor Standards (Aug 2018), (41 U.S.C. chapter 67).

(xiii) XX (A) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O. 13627).

_____ (B) Alternate I (March 2, 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).

(xiv) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (May 2014) (41 U.S.C. chapter 67.)

(xv) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements (May 2014) (41 U.S.C. chapter 67)

(xvi) 52.222-54, Employment Eligibility Verification (Oct 2015) (E. O. 12989).

(xvii) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015) (E.O. 13658).

(xviii) [52.222-62](#), Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).

(xix) (A) [52.224-3](#), Privacy Training (Jan 2017) ([5 U.S.C. 552a](#)).

(B) Alternate I (Jan 2017) of [52.224-3](#).

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

(xxi) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations. (JUN 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.

(xxii) 52.247-64, Preference for Privately-Owned U.S. Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)

The following have been deleted:

52.216-23	Execution And Commencement Of Work	APR 1984
252.217-7027	Contract Definitization	DEC 2012
252.232-7007	Limitation Of Government's Obligation	APR 2014

(End of Summary of Changes)