OTHER TRANSACTION AUTHORITY FOR PROTOTYPE AGREEMENT

BETWEEN

ASTRAZENECA PHARMACEUTICALS L.P. (Awardee)
1800 Concord Pike
Wilmington, Delaware 19850
DUNS Number: 876516568
CAGE Code: 36WK2

And

NATICK CONTRACTING DIVISION (Government)
110 Thomas Johnson Dr.
Frederick, MD 21702

Effective Date:	**9 October 2020**
Agreement Number:	**W911QY-21-9-0001**
Total Amount of the Agreement:	(b) (4)

Awardee

(b) (6)

Signature

(b) (6)

Printed Name

Executive Vice President,
Biopharmaceuticals Business Unit

Title

October 9, 2020

Date

Government

(b) (6)

(b) (6)

Printed Name

Agreements Officer

Title

09 Oct 2020

Date

This Other Transaction Authority for Prototype Agreement is entered into between the United States of America, hereinafter called the "Government", pursuant to and under U.S. Federal law, and AstraZeneca a large business, non-traditional defense contractor, hereinafter called the "Awardee". The United States of America and Awardee are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS, the Awardee is eligible for an Other Transaction Authority for Prototype Agreement in accordance with 10 USC § 2371b(d)(1)(A) as amended by the National Defense Authorization Act for Fiscal Year 2018 as they are non-traditional defense contractor;

WHEREAS, in accordance with 10 U.S.C. 2371b, The Department of Defense currently has authority to award "other transactions" (OTs) in certain circumstances for prototype projects that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the Armed Forces. To the maximum extent practicable, competitive procedures shall be used when entering into agreements to carry out projects under subsection (a);

WHEREAS, a prototype can generally be described as a physical or virtual model used to evaluate the technical or manufacturing feasibility or military utility of a particular technology or process, concept, end item, or system;

WHEREAS, this Agreement meets the criteria for a prototype project;

NOW THEREFORE, the Parties have agreed as follows:

ARTICLE 1. SCOPE

A. This Other Transaction Authority for Prototype Agreement (the "Agreement") is entered into between the Government and the Awardee on the Effective Date set forth above. For the avoidance of doubt, this Agreement is entered into pursuant to 10 U.S.C. § 2371b and is not a procurement contract governed by the Federal Acquisition Regulation (FAR), a grant, or a cooperative agreement. The FAR and the Defense Federal Acquisition Regulation Supplement (DFARS) apply only as specifically referenced herein. This Agreement is not intended to be, nor will it be construed as, forming, by implication or otherwise, a partnership, a corporation, or other business organization. This Agreement is not subject to the Bayh-Dole Act, 35 U.S.C. §§ 200-212.

B. The Parties agree that the sole purpose of this Agreement is to conduct a Phase 3 prophylaxis trial of a monoclonal antibody drug product (AZD7442) against the SARS-CoV-2 virus, technology transfer of manufacturing capabilities in preparation to scale the manufacturing process, rapid scale up of large-scale manufacturing, and delivery of 100,000 doses by (b) (4) [redacted], to include stockpiling and development of a distribution process capable of delivering AZD 7442 to point of care facilities, (hereinafter referred to as the "Prototype Project" or "Technology"). Consistent with the Government's objectives under Operation Warp Speed ("OWS"), AstraZeneca will exercise commercially reasonable efforts to employ its proprietary manufacturing technology and processes, in a manner compliant with applicable laws and regulations, including 21 CFR 210 and 211 and the Drug Supply Chain Security Act ("DSCSA") (to the extent required for COVID-19 medical countermeasures, as defined by relevant U.S. Food and Drug Administration ("FDA") guidance), to manufacture and deliver the AZD7442 drug product. The Awardee shall develop the Prototype Project as described in the Awardee's Statement of Work (SOW), which is incorporated herein and attached hereto as Appendix A.

C. This effort constitutes a prototype project because the project will be used to evaluate the technical feasibility during the ongoing COVID-19 pandemic and unprecedented threats to several components of the Prototype Project. In addition, this is a prototype project because AstraZeneca will demonstrate and prove-out the at-scale, multi-lot proprietary manufacturing activities in order to assess the feasibility to support the necessary quantity of safe and effective regimens required for treatment of the U.S. population.

D. The Prototype Project will be deemed successful where the Awardee's efforts meet the key technical requirements and are sufficient to meet an FDA Emergency Use Authorization (EUA) or licensure and/or has demonstrated capability to rapidly manufacture and deliver (b) (4) of AZD7442 product. Follow on production pursuant to 10 U.S.C. § 2371b is anticipated to be 1 million doses, which the Parties agree to negotiate such terms in good faith pursuant to a separate agreement.

ARTICLE 2. Term and Termination.

A. Term: The Term of this Agreement commences upon the Effective Date and extends through final payment. This Agreement is anticipated to end on the later of (i) nineteen (19) months after the Effective Date and (ii) issuance of the final clinical study report for the Phase 3 prophylaxis trial of AZD7442. A transaction for a prototype project is complete upon the written determination of the appropriate official for the matter in question that efforts conducted under a Prototype OT: (1) met the key technical goals of a project, or (2) accomplished a particularly favorable or unexpected result that justifies the completion of the prototype.

B. Termination for Convenience, Safety or Product Failure: The Government may terminate this Agreement for any or no reason by providing at least ninety (90) calendar days' prior written notice to the Awardee. The Government and Awardee will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination for convenience, consistent with the terms of this Agreement.

In addition, in the event that AstraZeneca notifies the Government of a Product Failure, then either Party may notify the other Party of its intent to terminate this Agreement, which termination shall be effective thirty (30) days after the date of such notice. As used herein, "Product Failure" means: (a) the Product presents a risk of death, a life-threatening condition or a serious safety or health concern to patients; (b) the Product fails to achieve the end points in its pivotal clinical trials for the treatment of SARS-CoV-2 infection in patients such that AstraZeneca's receipt of Regulatory Approval for the Product for such indication in the United States is not reasonably likely based upon such clinical trial results; or (iii) AstraZeneca receives a final unconditional non-approval letter from the FDA with respect to the Product that has rendered AstraZeneca's receipt of Regulatory Approval for the Product in such country not reasonably likely.

AstraZeneca shall have no liability to repay the Government for milestone payments made prior to the notification of termination. With respect to milestones which have not been completed, AstraZeneca shall be entitled to payment based on a percentage of the work performed toward said milestones, plus reasonable charges that AstraZeneca can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. By way of example, these costs may include, but are not necessarily limited to, costs associated with non-cancellable agreements with vendors to obtain manufacturing capacity or supplies in the performance of this prototype project agreement. AstraZeneca 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 AstraZeneca's records (but, for clarity, does not limit any other rights of the Government to audit AstraZeneca's records). AstraZeneca shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

From and after the effective date of any such termination, AstraZeneca shall have no further obligation to deliver any AZD7442 doses, and the Government shall have no further obligation to accept any such doses for delivery.

The Government and the Awardee will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination, including disposition of materials acquired for research use, consistent with the terms of this Agreement. Failure of the Parties to agree to a reasonable adjustment will be resolved pursuant to Article 5.H (Disputes). In the event of termination, the Parties shall negotiate in good faith a reasonable wind-down plan and neither Party shall have any continuing obligations to perform under the Agreement except as otherwise specified herein.

C. Termination for Cause: If the Awardee materially fails to comply with the provisions of this Agreement, the Agreement Officer (AO), after issuance of a cure notice and failure of the Awardee to cure the defect within ten (10) business days or the time allowed by the AO after Awardee's receipt of the cure notice, whichever is longer, may take one or more of the following actions as appropriate:

i. temporarily withhold payments pending correction of the deficiency,
ii. disallow all or part of the cost of the activity or action not in compliance,
iii. wholly or partly suspend or terminate this Agreement,
iv. withhold further funding, or
v. take any other legally available remedies.

D. Survival: In the event of Termination, all rights, obligations, and duties hereunder, which by their nature or by their express terms extend beyond the expiration or termination of this Agreement, including but not limited to warranties, indemnifications, intellectual property (including rights to and protection of Intellectual Property and Proprietary Information), and product support obligations shall survive the expiration or termination of this Agreement.

ARTICLE 3. Project Management.

A. Program Governance: The Awardee is responsible for the overall management of the project development program and related decisions. The Government will have continuous interaction with the Awardee. The Awardee shall provide access to project results in accordance with the Awardee's Project Timeline located in Appendix B.

B. Project Managers: The Awardee and the Government will each designate a Project Manager responsible for facilitating the communications, reporting, and meetings between the Parties. Each Party will also designate an alternate to the Project Manager, in case the primary Project Manager is unavailable. See Project Manager/Alternate Project Manager point of contact information for each respective party below:

Awardee Project Managers

Primary Project Manager:	Alternate Project Manager:
(b) (6)	(b) (6)
Director Global Project Management One MedImmune Way Gaithersburg, MD 20878 United States of America (b) (6)	Head of Biopharmaceuticals Project Management One MedImmune Way Gaithersburg, MD 20878 United States of America Ph: (b) (6)

	(b) (6)

Government Project Managers (GPM)

Primary Project Manager:	Alternate Project Manager:
(b) (6)	

C. Key Personnel: The Awardee's organization shall be established with authority to effectively complete the deliverables. The key personnel listed in Appendix C are considered to be critical to the successful performance of this Agreement. Prior to replacing these key personnel, the Awardee shall provide written notification to the AO. The Awardee shall demonstrate that the qualifications of the proposed substitute personnel are generally equivalent to or better than the qualifications of the personnel being replaced.

D. Subaward Approval: Modifications to subawards and/or new subcontracts under this Agreement that could reasonably impact the technical approach proposed and accepted by the Government require the approval of the AO prior to being executed.

E. Agreements Officer's Representative: The AO has assigned an Agreements Officer's Representative (AOR) for this agreement. The Awardee will receive a copy of the written designation outlining the roles and responsibilities of the AOR and specifying the extent of the AOR's authority to act on behalf of the AO. The AOR is not authorized to make any commitments or changes that will affect price, quality, quantity, delivery, or any other term or condition of the contract.

ARTICLE 4. Agreement Administration.

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

Government Representatives:

Agreements Officer (AO)
(b) (6)
ACC-APG-Fort Detrick
110 Thomas Johnson Dr.
Frederick, MD 21702
(b) (6)

Other Transaction Agreement Specialist (OTAS)
(b) (6)
ACC-APG-Fort Detrick
110 Thomas Johnson Dr.
Frederick, MD 21702
(b) (6)

Agreements Officer Representative (AOR):

(b) (6)
CBRN Division
Biomedical Advanced Research and Development Authority Kristen.herring@hhs.gov
(b) (6)

Awardee Representatives:

Primary Contact:
(b) (6)
Director, Business Planning & Ops
One MedImmune Way Gaithersburg, MD 20878 United States of America
(b) (6)

Alternate Contact:
(b) (6)
Head of Transactions, BD&L, Biopharmaceuticals R&D
(b) (6)

ARTICLE 5. Performance Objectives and Changes.

A. Statement of Work (SOW): The SOW, Appendix A, describes the scope of activities that will be undertaken by the Awardee to achieve the objective.

B. Recommendations for Modifications: At any time during the term of this Agreement, progress or results may indicate that a change in the SOW would be beneficial to the project objectives. Recommendations for modifications, including justifications to support any changes to the SOW, will be documented in a letter and submitted by Awardee to the GPM with a copy to the AO. This letter will detail the technical, chronological and financial impact, if any, of the proposed modification to the project. Any resultant modification is subject to the mutual agreement of the Parties. The Government is not obligated to pay for additional or revised costs unless and until this Agreement is formally revised by the AO and made part of this Agreement. Any modification to this Agreement to account for recommended changes in the SOW or Payable Milestones will be considered a supplemental agreement.

C. Review of Recommendations: The AO will be responsible for the review and verification of any recommendations to revise or otherwise modify the Agreement, the SOW, the milestone payments, or other proposed changes to the terms and conditions of this Agreement.

D. Minor Modifications: The Government may make minor or administrative Agreement modifications unilaterally (e.g., changes in the paying office or appropriation data, changes to Awardee personnel proposed by Awardee, etc.).

E. Amending the Agreement: The Government will be responsible for effecting all modifications to this Agreement, with the concurrence of the Awardee for modifications that are not minor or administrative. Administrative and material matters under this Agreement will be referred to AO.

F. Modification Communications: No other communications, whether oral or in writing, that purport to change this Agreement are valid.

G. Government Property: If applicable, terms and conditions applicable to Government Property shall be incorporated through Appendix D.

H. Disputes: For any disagreement, claim, or dispute arising under this Agreement, the parties shall communicate with one another in good faith and in a timely and cooperative manner. Whenever disputes, disagreements, or misunderstandings arise, the parties shall attempt to resolve the issue by discussion and mutual agreement as soon as practicable. Failing resolution by mutual agreement, the aggrieved party shall request a resolution in writing from the AO. The AO will review the matter and render a decision in writing within sixty (60) calendar days. Thereafter, either party may pursue any right or remedy provided by law in a court of competent jurisdiction as authorized by 28 U.S.C. 1491. Alternately, the parties may agree by mutual consent to explore and establish and Alternate Disputes Resolution procedure to resolve this dispute. The Awardee shall proceed diligently with performance under this agreement pending resolution of the dispute.

Either Party may recover interest on any amounts submitted for payment and denied during the disputes process. Interest on an amount found due on a disagreement, claim or dispute shall accrue from the date the payment was due until such time as the claim is paid and, in the event such interest is payable by the Government, shall be payable and paid to the Awardee in accordance with the Prompt Payment Act. Simple interest shall accrue and be paid at the same rate as that which the Secretary of the Treasury shall specify as applicable for each successive 6-month period under the Prompt Payment Act.

ARTICLE 6. Inspection/Acceptance

A. Inspection: The Government has the right to inspect and test all work called for by this Agreement, to the extent practicable at all places and times, including the period of performance, and in any event before acceptance. The Government may also inspect the premises of the Awardee or any subawardee engaged after the Effective Date, with seven (7) days advance notice to the Awardee, or fourteen (14) days advance notice to any such subawardee. The scope and duration of any such Government inspection will be mutually agreed between the Parties in writing in advance, such agreement not to be unreasonably withheld. The Government shall perform inspections and tests in a manner that will not unduly delay the work and will be subject to the Awardee's or subawardee's, as applicable, policies and procedures regarding security and facility access at all times while on the premises. If the Government performs any inspection or test on the premises of the Awardee or a subawardee, the Awardee shall furnish and shall require subawardees to furnish, at no increase in price, all reasonable facilities and assistance for the safe and convenient performance of these duties. Except as otherwise provided in the Agreement, the Government shall bear the expense of Government inspections or tests made at other than the Awardee's or subawardee's premises.

B. Acceptance: The Government shall inspect/accept or reject the work as promptly as practicable after completion/delivery, unless otherwise specified in the Agreement. Government failure to inspect and accept or reject the work shall not relieve the Awardee from responsibility, nor impose liability on the Government, for nonconforming work. Work is nonconforming when it is defective in material or workmanship or is otherwise not in conformity with Agreement requirements. The Government has the right to reject nonconforming work. Inspection/Acceptance of the supply deliverables should not exceed 90 days after completion.

ARTICLE 7. Financial Matters

A. Generally. This Agreement is a Milestone payment type Other Transaction Authority agreement, unless otherwise denoted. The payments provided under this Agreement are intended to compensate the Awardee for performance under this Agreement. The Awardee shall use its best efforts to complete the Prototype Project based on the estimated cost.

B. Milestones. Delineated in Appendix B of this agreement.

Recipient will provide AOR and AO notification of milestone success and any documentation that supports successful completion of the milestone. Within ten (10) business days of receipt, the AOR will either, 1) confirm milestone completion and authorize the Recipient to invoice against the completed milestone or, 2) notify the Recipient of any deficiencies, additional documentation or clarifications reasonably needed by the Government to complete its review of the milestone. The Parties agree that payments will be made upon the AOR's acceptance of completed milestones. These payments reflect value received by the Government toward the accomplishment of the Prototype Project goals.

C. Obligation. Under no circumstances shall the Government's financial obligation exceed the amount obligated in this Agreement or by amendment to the Agreement. The amount of Government funds obligated and available for payment under this Agreement and subsequent modifications shall be set forth in the Government's electronic system (PD2). A PD2 version of the Agreement will be issued for reporting and payment purposes. The Government may incrementally fund this agreement. The Government is not obligated to provide payment to the Awardee for amounts in excess of the amount of obligated funds allotted by the Government.

D. Invoicing and Payment. After accomplishment of each milestone, the Awardee will submit the corresponding invoice through a Government provided invoicing and payment system, as detailed in Section 7.E. In addition, the Awardee will provide notification to the AOR that a payment has been submitted. Payments will be made by the cognizant Defense Finance and Accounting Services office, as indicated below, in accordance with the Prompt Payment Act. Payments shall be made in the amounts set forth in the milestone table in Section 7.B, provided the AOR has verified the completion of the applicable milestones. The Government will pay AstraZeneca in US dollars.

The amounts stated as payable by the Government to the Awardee pursuant to this Agreement are stated exclusive of any Taxes that may be chargeable in respect of that payment and shall not be reduced on account of any Taxes unless required by applicable law. The Awardee alone shall be responsible for paying any and all Taxes (other than withholding Taxes required to be paid by the Government under applicable law) levied on account of, or measured in whole or in part by reference to, any payments it receives. If the Awardee is entitled under any applicable Tax treaty to a reduction of rate of, or the elimination of, or recovery of, applicable withholding Tax, it shall deliver to the Government or the appropriate governmental authority (with the assistance of the Government to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve the Government of its obligation to withhold Tax, and the Government shall apply the reduced rate of withholding, or dispense with the withholding, as the case may be, to the extent it complies with the applicable Tax treaty. If, in accordance with the foregoing, the Government withholds any amount, it shall make timely payment to the proper Taxing Authority of the withheld amount, and send to the Awardee proof of such payment within 90 days following that payment.

As used herein: **Taxes** means all taxes of any kind, and all charges, fees, customs, levies, duties, imposts, required deposits or other assessments, including all federal, state, local or foreign net income, capital gains, gross income, gross receipt, property, franchise, sales, use, excise, withholding, payroll, employment, social

security, worker's compensation, unemployment, occupation, capital stock, transfer, gains, windfall profits, net worth, asset, transaction and other taxes, and any interest, penalties or additions to tax with respect thereto, imposed upon any person by any Taxing Authority or other governmental authority under applicable law, whether disputed or not, and including any obligation to indemnify or otherwise assume or succeed to the Tax liability of any other person by law, by contract or otherwise. **Taxing Authority** means any governmental authority or any subdivision, agency, commission or authority thereof or any quasi-governmental body exercising tax regulatory authority.

The Awardee shall maintain adequate records to account for all funding under this Agreement. Neither the Cost Accounting Standards nor any other aspect of the Federal Acquisition Regulation or its supplements apply to AstraZeneca's accounting of costs under this Agreement. Cost shall be accounted for in accordance with AstraZeneca's commercial accounting practices. AstraZeneca has an established and agrees to maintain an established accounting system which complies with International Financial Reporting Standards and the requirements of this Agreement, and shall ensure that appropriate arrangements have been made for receiving, distributing and accounting for Federal funds. An acceptable accounting system is one in which all costs, cash receipts and disbursements for which AstraZeneca is entitled to reimbursement under Article 6 are controlled and documented properly.

E. WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (MAY 2013)

a. Definitions. As used in this clause—
   i. Department of Defense Activity Address Code (DoDAAC) is a six position code that uniquely identifies a unit, activity, or organization.
   ii. Document type means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).
   iii. Local processing office (LPO) is the office responsible for payment certification when payment certification is done external to the entitlement system.

b. Electronic invoicing. The WAWF system is the method to electronically process vendor payment requests and receiving reports, as authorized by DFARS 252.232- 7003, Electronic Submission of Payment Requests and Receiving Reports.

c. WAWF access. To access WAWF, the Awardee shall (i) have a designated electronic business point of contact in the System for Award Management at https://www.acquisition.gov; and (ii) be registered to use WAWF at https://wawf.eb.mil/ following the step-by-step procedures for self-registration available at this website.

d. WAWF training. The Awardee 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 Awardee must use the following information when submitting payment requests and receiving reports in WAWF for this Agreement:

   i. Document type. The Awardee shall use the following document type: Voucher
   ii. Inspection/acceptance location. The Awardee shall select the following inspection/acceptance location(s) in WAWF, as specified by the contracting officer.

iii. Document routing. The Awardee 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

Field Name in WAWF	***Data to be entered in WAWF***
Pay Official DoDAAC	**HQ0490**
Issue By DoDAAC	**W911QY**
Admin DoDAAC	**W911QY**
Inspect By DoDAAC	**W56XNH**

g. Payment request and supporting documentation. The Awardee shall ensure a payment request includes appropriate contract line item and subline item descriptions of the work performed or supplies delivered, costs, fee (if applicable), and all relevant back-up documentation in support of each payment request.

h. WAWF email notifications. The Awardee shall enter the email address identified below in the "Send Additional Email Notifications" field of WAWF once a document is submitted in the system.

(b) (6) [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

i. WAWF point of contact.

i. The Awardee may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

ii. For technical WAWF help, contact the WAWF helpdesk at 866-618-5988.

F. Comptroller General Access to Records: To the extent that the total Government payments under this Agreement exceed $5,000,000, the Comptroller General, at its discretion, shall have access to and the right to examine records of any Party to the Agreement or any entity that participates in the performance of this Agreement that directly pertain to, and involve transactions relating to, the Agreement for a period of three (3) years after final payment is made. This requirement shall not apply with respect to any Party to this Agreement or any entity that participates in the performance of the Agreement, or any subordinate element of such Party or entity, that has not entered into any other agreement (contract, grant, cooperative agreement, or "other transaction") that provides for audit access by a government entity in the year prior to the date of this Agreement. This paragraph only applies to any record that is created or maintained in the ordinary course of business or pursuant to a provision of law. The terms of this paragraph shall be included in all sub-agreements to the Agreement other than sub-agreements with a component of the U.S. Government. The Comptroller General may not examine records pursuant to a clause included in an agreement more than three years after the final payment is made by the United States under the agreement.

ARTICLE 8. Deliverables

A. Deliverables Table

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
01	**Meetings**			
01.1	Post Award Teleconference	The Awardee shall complete an initial teleconference after agreement award 1. Outline activities for the next 30 days 2. Discuss agenda items for the post-award Kickoff Meeting (01.2)	•Within one week of Agreement award •Awardee shall provide agenda and establish a teleconference number at least 3 business days in advance of the teleconference unless notified that BARDA will supply one •AOR edits/approves and instructs Awardee to distribute agenda prior to meeting by at least 2 business days •Awardee provides meeting minutes to AOR within 3 business days after the meeting •AOR reviews, comments and approves minutes within 10 business days	Government Purpose
01.2	Kickoff Meeting	The Awardee shall complete a Kickoff meeting after agreement award	•Within a month of agreement award, pending concurrence by the agreements officer •Awardee shall provide itinerary and agenda at least 5 business days in advance of site visit or virtual meeting •AOR edits/approves and instructs Awardee to distribute agenda prior to meeting by at least 3 business days •Awardee provides meeting minutes to AOR within 3 business days after the meeting •AOR reviews, comments, and approves minutes within 10 business days	Government Purpose
01.3	Every 2 weeks Teleconference	The Awardee 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	•Awardee provides agenda to AOR no later than 2 business days in advance of meeting •AOR edits/approves and instructs Awardee to distribute agenda prior to meeting •Awardee distributes agenda and presentation materials at least 24 hours in advance •Awardee provides meeting minutes to AOR within 3 business days of the meeting •AOR reviews, comments, and approves minutes within 6 business days •Updates to include: BARDA Awardee Clinical Trials Information Sheet, forecast of activities across each WBS number as	Government Purpose

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
			well as updates on planned regulatory submissions.	
01.4	Quarterly Meetings	At the discretion of the government the Awardee 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 Awardee or sub-awardees. Face-to-face meetings shall alternate between Washington DC and Awardee, sub-awardee sites. The meetings will be used to discuss agreement progress in relation to the Program Management deliverables described below as well as study designs, technical, regulatory, and ethical aspects of the program.	•Awardee shall provide itinerary and agenda at least 5 business days, and presentation materials at least 3 business days in advance of site visit •AOR edits/approves and instructs Awardee to distribute agenda prior to meeting by at least 3 business days •Awardee provides meeting minutes to AOR within 3 business days after the meeting •AOR reviews, comments, and approves minutes within 10 business days	Government Purpose
01.5	FDA Meeting Minutes and other communications with FDA	As described in Article 13	•Awardee shall notify BARDA 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 Awardee shall forward initial Awardee and FDA-issued draft minutes and final minutes of any meeting with the FDA to BARDA within (b) (4) of receipt	Limited
01.6	Daily check in with project staff for **COVID-19 Agreement**	Upon request of the Government, the Awardee shall participate in a daily check-in update with the Project Managers and additional project staff as needed(via teleconference or email). Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the Government, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.	•Preparation of materials will not be required but may be provided on an ad hoc basis as data or circumstances occur •No agenda will be required for the meeting •No meeting minutes are required •Awardee will provide bulleted email updates following any call or in lieu of a call by 2PM for that day	Government Purpose
02	**Technical Reporting**			
02.1 (Monthly)	Monthly Progress Reports	A consolidated submission of all slides and data presented at the bi-weekly telecons will serve as the monthly report	•Monthly reports shall be submitted on or before the 20th day of the month covering the preceding month	Government Purpose*
02.2 (Milestone)	Milestone Reports	Milestone reports shall be cross-referenced to the Work Breakdown Structure (WBS), Statement of Work (SOW) and Integrated Master Schedule (IMS). As applicable, an Executive Summary highlighting the progress,	•Milestone reports shall be submitted upon the completion of each milestone and include all associated deliverables. The AOR and AO will review the monthly reports with the Awardee and provide feedback	Government Purpose*

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
		issues and relevant manufacturing, non-clinical, clinical and regulatory activities. The Executive Summary should highlight only critical issues for that reporting period and resolution approach; limited to 2 pages	•Awardee shall provide FINAL versions of reports within (b) (4) after receiving BARDA comments/edits	
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 report shall be duly marked as 'Draft' 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	•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 •AOR will provide feedback on draft report within (b) (4) of receipt, which the Awardee 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.	Government Purpose*
2.5	FDA Manufacturing Reports	At BARDA's request, Awardee shall provide Manufacturing Reports to BARDA for review and comment prior to submission to FDA The AOR and AO reserve the right to request within the PoP a non-proprietary Manufacturing Report for distribution within the USG	•Awardee will submit Manufacturing Reports at least (b) (4) prior to FDA submission or within a shorter timeframe upon Awardee request and approval from the AOR •The Government will provide written comments to the manufacturing report within (b) (4) after the submission •If corrective action is recommended, Awardee must address all concerns raised by BARDA in writing •Awardee shall consider revising reports to address BARDA's concerns and/or recommendations prior to FDA submission	Limited
02.6	Product Development Source Material and Manufacturing Reports	The Awardee shall submit a detailed spreadsheet regarding critical project materials that are sourced	•Awardee will submit Product Development Source Material Report	Limited

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
	and Projections	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 Awardee 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.	○ 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. •Awardee 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 (b) of award/modification. Updates to be provided weekly in advance of commercial-scale manufacturing and daily once material for use in response operations begins manufacture. • The Government will provide written comments to the Product Development Source Material and Manufacturing Report within (b) (4) after the submission •If corrective action is recommended, Awardee 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.	
02.7	Awardee Locations	The Awardee 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-awardees.	Awardee will submit Work Locations Report: •Within (b) (4) (b 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	Limited

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
2.8	Pandemic Management Plan	A pandemic facility and/or operational management plan including change procedures from normal to pandemic operations Awardee will prepare an operational plan to continue operations in the event of a declared pandemic emergency.	Awardee will submit Pandemic Management Plan: • Draft within (b) of award • Final within (b) of award	Government Purpose
02.9	Final Data Submission Package	Awardee must submit a data package consisting of all raw data produced under this Agreement. This submission package must be delivered in a non-proprietary format. If clinical trial data is included, that data must be provided consistent with applicable privacy laws to protect personally identifiable information (PII).	Awardee will submit at least (b) prior to Agreement end date. Partial data-sets may also be requested for delivery prior to submission of the Final Data Submission Package.	Government Purpose*
02.10	Supplemental Technical Documents, Raw Data, Tabulation Data (e.g., CDISC-compliant SDTM SAS XPT datasets), or Data Analysis (e.g., CDISC-compliant ADaM SAS XPT datasets)	Upon request and also as part of deliverables the Awardee 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), or data report to BARDA.	Awardee shall provide the Technical Documents upon request from the AO or AOR	Government Purpose*

02.11	Supply Chain and Distribution Tracking	Distribution Concept of Operations. BARDA, and MCM Manufacturers play an important role in the distribution of therapeutics to the American people under a nationwide response. BARDA will work with the manufacturer to monitor what is in the manufacturing pipeline using the enclosed dose tracking templates (see above). Awardee will relay final drug product information as it is being released to the BARDA/ASPR for allocation and ordering by state public health departments. This information will be returned to BARDA, the awardee and distributor. Distributors will use that information to ship therapeutics in bulk to sites of administration/end user..	Provide the following information in order to coordinate the movement and delivery of AZD7442 from manufacturing locations sites of administration/end user :
			• Provide Points of Contact information (name, title, phone, email) for manufacturing / supply chain personnel for each manufacturing, CMO, storage and distribution locations:
			  • Head of Manufacturing
			  • Production Planning
			  • Logistics
			  • Distribution
			  • Labeling
			• Provide therapeutic labeling, packaging and distribution information as soon as it becomes available. At a minimum, include the following:
			  • Primary Container Information
			  • Number of doses per primary container
				Limited

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
			• Unit of Sale (carton, box, package, other) • Quantity per Unit of Sale • National Drug Code (NDC) or NDC-like code under EUA • Unit of Sale dimensions (H,W, L) • Unit of Sale weight • Intermediate Package • Intermediate Package dimensions • Intermediate Package weight • Quantity Unit of Sale per pallet • Storage Requirements • Stability Information • Obtain concurrence on planned shipment protocols prior to transport • If therapeutic will require ultra-cold storage temperatures at the designated distribution centers, products should be packaged in 10-dose units to facilitate pick/pack process and reduce exposure of workers to ultra-cold temperatures. • Include the following DSCSA data elements, TI, TH and TS in packing lists. • Include the Agreement number on the packing list for all shipments • Include a copy of the MSDS (with QR code) in the packing list envelope with each shipment. • Send EDI 856 Advanced Shipment Notice for all products shipped to a USG directed location. Send electronic/scanned copies of all bulk shipment related documents to the AOR for three-way matching on the day shipment occurs.	
02.11a	Distribution Plan	This plan shall describe the Awardee's process to distribute EUA-or BLA-approved product to point of care facilities, necessary to	• [NLT 12/31/20]	Government Purpose

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
		meet the Government's need for administration. The plan shall comply with applicable provisions of the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov 27, 2013), taking into account FDA's regular guidance for the COVID-19 public health response.		
02.11b	Distribution Software	AZD 7422 distribution software	• (b) (4)	Government Purpose Rights Subject to determination consistent with DFARS 252.227-7014
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.")	• Plan will be delivered electronically within (b) of Agreement award to the AO and AOR	Limited
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	• Plan will be delivered electronically within (b) of Agreement award to the AO and AOR	Government Purpose
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	• Agreement will be signed by the USG and the manufacturer within (b of Agreement award • Agreement will be delivered	Limited

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
		until a quality agreement is in place.	electronically to the AO and AOR	
2.15	Release documentation for doses to be delivered	Certificate of Analysis Certificate of Compliance	• At least (b) prior to delivery	Government Purpose
2.15a	Batch Records	Batch records for drug substance and drug product	Documentation to be reviewed by USG and comments adjudicated prior to dose delivery at least (prior to delivery b	Limited
2.16	Security Plan	As described in Article 8.B(11)	• Within (b) (4) of award/definitization	Limited
2.17	Supply Chain Resiliency Plan	As described in Article 8.B(8)	• Within (b) (4) s of award/definitization	Limited
2.18	Manufacturing Data Requirements	As described in Article 8.B2(9)	• Within (b) (4) of award/definitization	Limited
03	**Audits**			
03.1	BARDA Audit	Awardee shall accommodate periodic or ad hoc site visits by BARDA. If BARDA, the Awardee, or other parties identifies any issues during an audit, the Awardee shall capture the issues, identify potential solutions, and provide a report to BARDA	•If issues are identified during the audit, Awardee shall submit a report to BARDA detailing the finding and corrective action(s) within (b) (4) of the audit •AOR and AO will review the report and provide a response to the Contractor with (b) (4) •Once corrective action is completed, the Awardee will provide a final report to BARDA	Government Purpose
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 Awardee shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Awardee shall provide the AOR and AO 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 Awardee shall also provide copies of any FDA audits received from subawardees that occur as a result of this contract or for this product. The Awardee shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector	•Awardee shall notify AO and AOR 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 •Awardee shall provide copies of any FDA audit report received from subawardees that occur as a result of this contract or for this product within 1 business day of receiving correspondence from the FDA or third party •Within (b) (4) ays of audit report, Awardee shall provide AO with a plan for addressing areas of nonconformance, if any are identified	Limited
03.3	QA Audits	BARDA reserves the right to participate in QA audits performed by the Awardee. Upon completion of the audit/site visit the Awardee shall	•Awardee shall notify AO and AOR a minimum of (b) (4) days in	Limited

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
		provide a report capturing the findings, results and next steps in proceeding with the subawardee. If action is requested of the subawardee, 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 Awardee shall provide responses from the subawardees to address these concerns and plans for corrective action	advance of upcoming, audits/site visits of subawardees •Awardee shall notify the AOR and AO within (b) (4) of report completion. •AOR and AO will review the report and provide a response to the Awardee with (b) (4)	
03.4	Risk Management Plan (RMP)	The Awardee 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	•A Draft is due (b) (4) within contract award; updates to the RMP are due concurrent with Monthly Technical Progress Reports. The Awardee 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 Awardee with a list of concerns in response plan submitted •Awardee must address, in writing, all concerns raised by BARDA within (b) of Awardee's receipt of BARDA's concerns	Government Purpose
03.5	Integrated Master Schedule (IMS)	The Awardee shall provide an IMS that illustrates project tasks, dependencies, durations throughout the period of performance, and milestones (GO/NO-GO). The IMS must map to the WBS, and provide baseline, and actual or forecast dates for completion of tasks	•The IMS is to be submitted in both PDF and Microsoft Project Form to the AOR •The first Draft of the IMS is due (b) within contract award •The Government will request revisions within (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 within (b) of contract award, updates are due weekly, and any significant change (I.e. a change which would impact the schedule by greater than one week) must be reported immediately to the AOR and/or designee.	Government Purpose
03.6	Deviation Notification and Mitigation Strategy	Process for changing IMS activities associated with cost and schedule as baselined. Awardee shall notify BARDA of significant proposed changes the IMS defined as increases in cost above 5% or schedule slippage of more than 30	•Due at least (b) (4) prior to the Awardee anticipating the need to implement changes	Government Purpose

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
		days, which would require a PoP extension. Awardee shall provide a high level management strategy for risk mitigation		
03.7	Incident Report	Awardee 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. "Significant" is frequently defined as a 10% or greater cost or schedule variance within a control account, but should be confirmed in consultation with the AOR. 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	•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 AOR and AO •Additional updates due to AOR and AO within (b) (4) of additional developments •Awardee shall submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues •If corrective action is deemed necessary, Awardee must address in writing, its consideration of concerns raised by BARDA within (b) (4) of receiving such concerns	Limited
09	**Advanced R&D Products**			
09.1	Technical Documents	Upon request, Awardee shall provide AO and AOR with deliverables from the following contract funded activities: quality agreements between Awardees and sub-awardees, 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 AO and AOR reserve the right to request within the PoP a non-proprietary technical document for distribution within the Government	•Awardee shall provide technical document within (b) (4) of AO or AOR request. Awardee can request additional time on an as needed basis •If corrective action is recommended, the Awardee must address, in writing, concerns raised by BARDA in writing	Government Purpose*
09.2	Publications	Any manuscript or scientific meeting abstract 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.9 and H.24	• Awardee must submit all manuscript or scientific meeting abstract to PO and AO prior to submission/presentation by (b) (4) for manuscripts and (b) (4) for abstracts or posters • Awardee must address in writing all concerns raised by BARDA in writing • Final submissions shall be submitted to BARDA concurrently or no later than (b) (4) of its submission	Limited
10	**Regulatory Documents**			
10.1	FDA Correspondence	As described in Article 13	•Awardee shall provide copies of any FDA correspondence within (b) (4) (b) of correspondence	Limited

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights
10.2	FDA Submissions	As described in Article 13, the Awardee shall provide BARDA the opportunity to review and comment upon all draft submissions before submission to the FDA. Awardee shall provide BARDA with an electronic copy of the final FDA submission. All documents shall be duly marked as either "Draft" or "Final"	• Awardee shall submit draft FDA submissions to BARDA at least [redacted] prior to FDA submission or within a shorter timeframe upon Awardee request and approval from the AOR • BARDA will provide feedback to Awardee within (b) (4) of receipt or within a shorter timeframe upon Awardee request and approval from the AOR. • The Awardee must address, in writing, its consideration of all concerns raised by BARDA prior to FDA submission • Final FDA submissions shall be submitted to BARDA concurrently or no later than (b) (4) of submission	Limited
10.3	EUA Filing	The Awardee shall provide a copy of any request for EUA submitted to the FDA	• Within (b) (4) after submission to the FDA	Limited
10.4	BLA Filing	The Awardee shall provide a copy of the BLA submitted to the FDA	• Within (b) (4) after submission to the FDA	Limited
10.5	Provision of Public Law 115-92 Sponsor Authorization Letter	The Awardee shall submit Public Law 115-92 Sponsor Authorization Letter that will be delivered to the designated OWS POC(s).	• Within (b) of award	All information provided under the authorization letter related to Public Law 115-92 shall be delivered with the data rights listed in this Deliverable Table.
11	Press Releases	Awardee agrees to accurately and factually represent the work conducted under this contract in all press releases	• Awardee shall ensure that the AO 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 Awardee 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 one (1) calendar day prior to its release	Government Purpose

* 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) [redacted]

B. Detailed Description of Select Contract Deliverables

1. 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.

2. Draft Report for Clinical and Non-Clinical Studies and Final Report for Clinical and Non-Clinical Studies

I. The clinical trial reports shall follow the format of International Conference on Harmonization document ICH E3 "Guideline for Industry on Structure and Content of Clinical Study Reports"

II. Draft Final Report for Clinical and Non-Clinical Studies funded by this Agreement will be submitted to the Agreements Officer's Representative (AOR) and Agreements Officer (AO) for review and comment within the time frames set forth in the table ("Summary of Agreement Deliverables") under ARTICLE F.2.

III. Subawardee prepared reports received by the Awardee shall be submitted to the Agreements Officer's Representative (AOR) and Agreements Officer (AO) for review and comment as set forth by the table in this Article. Awardee shall consider revising reports to address BARDA's recommendations prior to FDA submission.

IV. The Government shall provide written comments to the Draft Final Report for Clinical and Non-Clinical Studies in accordance with the dates set forth by the table in this Article.

V. The comprehensive Final Report for Clinical and Non-Clinical Studies will be submitted to the Agreements Officer and the Agreements Officer's Representative set forth by the table in this Article.

3. Ad Hoc Meetings

In addition to the bi-weekly meetings and monthly program updates, additional ad hoc meetings to address specific issues or to convey time-sensitive updates or scientific data related to the program will be held.

4. Regulatory Documentation and Technical Data Packages

As indicated in Article 13, the Awardee shall work in consultation with the Government Regulatory and Quality Affairs staff for the development of all regulatory submission packages to the FDA and include Government Regulatory and Quality Affairs staff in all formal discussions with the FDA. The Awardee shall provide the Government copies of all technical data generated by the Awardee prior to and during performance of the project, necessary to pursue FDA approval and notify the Government of FDA decisions as these take place.

If applicable, the Awardee shall prepare an IND/BLA in the Electronic Common Technical Document (eCTD) format for submission to the FDA and the Government. The awardee shall submit all pre-IND, IND, pre-EUA, and/or BLA report submissions to the AOR for review.

All documentation submitted to the Government must have quality oversight from an appropriate, independent Quality group not reporting to the executing management group (for example; clinical trials group, data management group, etc.).

5. Miscellaneous Data Submissions

If applicable, the Awardee must submit to the Government all Point Papers, Briefings, Technical Performance Plans (TPP), Program Development Plans (PDP), Regulatory Strategy, Technology Transfer Report and Gap Analysis, Formulation Development, Feasibility and Optimization Reports, United States Army Medical Research and Material Command Animal Care and Use Review Office (USAMRDC ACURO) Approvals, Human Resources Operations Branch (HROB) Approvals, Technical Presentations and Publications, and any formal technical reports that have been prepared for eventual submission to FDA or other regulatory agencies. Examples include the following reports related to: pharmaceutical development, manufacturing development, manufacturing validation, completed batch records, certificates of analysis, analytical development and validation, drug substance and product stability, nonclinical testing, and clinical testing. Examples include clinical performance and clinical quality documentation.

6. Work Breakdown Structure

Three-level WBS with costs and schedule (top level is program, level two (2) is phase, level three (3) are major tasks). For WBS level two (2), show breakdown for labor, material, and other indirect costs.

WBS shall be updated annually or thirty (30) calendar days after a Statement of Work modification. Government review/approval is fifteen (15) calendar days after receipt of first submittal. Provide changes to draft within ten (10) calendar days of such request. Provide final document within ten (10) calendar days after approval of changes is received.

7. Quality Agreement

The Awardee shall submit a quality agreement within (b) (4) of award for Government review. Upon acceptance the agreement is to be executed by both parties. The Awardee will ensure appropriate quality agreements are in place with applicable subawardees to enable the Awardee to comply with its quality obligations to the Government , in accordance with FDA guidance and regulations, including but not limited to the November 2016 Guidance for Industry, "Contract Manufacturing Arrangements for Drugs: Quality Agreements.

8. Supply Chain Resiliency Plan

The Awardee shall develop and submit within (b) (4) of Agreement 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 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 Awardee shall identify key equipment suppliers, their locations, local resources, and the associated control processes at the time of award. This document shall address planning and scheduling for active

pharmaceutical ingredients, upstream, downstream, component assembly, finished drug product and delivery events as necessary for the delivery of product.

a) Communication for these requirements shall be updated as part of an annual review, or as necessary, as part of regular contractual communications.

b) For upstream and downstream processing, both single-use and re-usable in-place processing equipment, and manufacturing disposables also shall be addressed. For finished goods, the inspection, labeling, packaging, and associated machinery shall be addressed taking into account capacity capabilities.

c) The focus on the aspects of resiliency shall be on critical components and aspects of complying with the Agreement delivery schedule. Delivery methods shall be addressed, inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the contractually agreed deliveries.

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

a) Production rates and lead times shall be understood and communicated to the Agreements Officer or the Agreements Officer's Representative as necessary.

b) Production throughput critical constraints should be well understood by activity and by design, and communicated to contractual personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.

Reports for critical items should include the following information:

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

The AO and AOR reserve the right to request un-redacted copies of technical documents provided in response to this subsection, during the period of performance, for distribution within the Government. Documents shall be provided within ten (10) days after AO issues the request. The Awardee may arrange for additional time if deemed necessary, and agreed to by the AO. The Government will have Limited Rights in any documents provided under this subsection.

9. Manufacturing Data Requirements

The Awardee shall submit within (b) (4) of execution of this OTA 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 Awardee to be used to submit such data, intended to ensure material development, which would include but not be limited to the following:

a. Storage/inventory of ancillary materials (vials, needles, syringes, etc.)

b. Shipment of ancillary materials (vials, needles, syringes, etc.)
c. Disposal of ancillary materials (vials, needles, syringes, etc.)
d. Seed development or other starting material manufacturing
e. Bulk drug substance and/or adjuvant production
f. Fill, finish, and release of product or adjuvant
g. Storage/inventory of starting materials, bulk substance, or filled/final product or adjuvant
h. Stability information of bulk substance and/or finished material
i. Shipment of bulk substance of final material
j. Disposal of bulk substance or final material

10. 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 AOR 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.

11. 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 (b) (4) of award. The Awardee shall also use commercially reasonable efforts to ensure all subawardees, consultants, researchers, etc. performing work on behalf of this effort, comply with all Government security requirements and Awardee security plans. However, the Government acknowledges that, in order to combat the global pandemic and launch AZD7442 as quickly as possible, the Awardee has entered into a number of contracts prior to the Execution Date. The Awardee will flow-down the provisions of the Security Plan to (i) all sub-agreements/contracts executed after the Execution Date, and (ii) all sub-agreements/contracts executed prior to the Execution Date which cover manufacturing/fill/finish/storage activities under this Agreement; provided that in no event will the Awardee be required to flow-down any provisions to any sub-awardee which has a pre-existing direct relationship with the Government. The Awardee will have a period of (b) (4) to amend any existing agreements to reflect these flow-down requirements or, in the alternative, to demonstrate the sub-awardee's material compliance with any such flow-down requirements.

The Government will review in detail and submit comments within (b) (4) to the Agreements Officer (AO) to be forwarded to the Awardee. The Awardee shall review the Draft Security Plan comments, and, submit a Final Security Plan to the U.S. Government within (b) (4) 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	• organization chart and responsibilities • written security risk assessment for site • threat levels with identification matrix (High, Medium, or Low) • enhanced security procedures during elevated threats • liaison procedures with law enforcement • annual employee security education and training program
Personnel Security	• policies and procedures • candidate recruitment process • background investigations process • employment suitability policy • employee access determination • rules of behavior/ conduct • termination procedures • non-disclosure agreements
Physical Security Policies and Procedures	• internal/external access control • protective services • identification/badging • employee and visitor access controls • parking areas and access control • perimeter fencing/barriers • product shipping, receiving and transport security procedures • facility security lighting • restricted areas • signage • intrusion detection systems • alarm monitoring/response • closed circuit television • product storage security • other control measures as identified
Information Security	• identification and marking of sensitive information • access control • storage of information • document control procedures • retention/ destruction requirements
Information Technology/Cyber Security Policies and Procedures	• intrusion detection and prevention systems • threat identification • employee training (initial and annual) • encryption systems • identification of sensitive information/media • password policy (max days 90) • lock screen time out policy (minimum time 20 minutes)

	• removable media policy • laptop policy • removal of IT assets for domestic/foreign travel • access control and determination • VPN procedures • WiFi and Bluetooth disabled when not in use • system document control • system backup • system disaster recovery • incident response • system audit procedures • property accountability
2. Site Security Master Plan Description: The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; IT Server Room; Product Storage Freezer/Room; and bio-containment laboratories.	
3. Site Threat / Vulnerability / Risk Assessment Description: The partner facility shall provide a written risk assessment for the facility addressing: criminal threat, including crime data; foreign/domestic terrorist threat; industrial espionage; insider threats; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies. The assessment should be updated annually.	
4. Physical Security Description:	
Closed Circuit Television (CCTV) Monitoring	a) Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored. b) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. c) Video recordings must be maintained for a minimum of 30 days. d) CCTV surveillance system must be on emergency power backup. e) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. f) Video recordings must be maintained for a minimum of 30 days. g) CCTV surveillance system must be on emergency power backup.
Facility Lighting	a) Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings. b) Lighting must have emergency power backup. c) Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.
Shipping and Receiving	a) Must have CCTV coverage and an electronic access control system. b) Must have procedures in place to control access and movement of drivers picking up or delivering shipments. c) Must identify drivers picking up Government products by government issued photo identification.

Access Control	a) Must have an electronic intrusion detection system with centralized monitoring. b) Responses to alarms must be immediate and documented in writing. c) Employ an electronic system (i.e., card key) to control access to areas where assets critical to the contract are located (facilities, laboratories, clean rooms, production facilities, warehouses, server rooms, records storage, etc.). d) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas. e) Must have a system that provides a historical log of all key access transactions and kept on record for a minimum of12 months. f) Must have procedures in place to track issuance of access cards to employees and the ability to deactivate cards when they are lost or an employee leaves the company. g) Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of 12 months. h) Should have written procedures to prevent employee piggybacking access i) to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access. j) Must have a written manual key accountability and inventory process. k) Physical access controls should present a layered approach to critical assets within the facility.
Employee/Visitor Identification	a) Should issue company photo identification to all employees. b) Photo identification should be displayed above the waist anytime the employee is on company property. c) Visitors should be sponsored by an employee and must present government issued photo identification to enter the property. d) Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises at all times.
Security Fencing	Requirements for security fencing will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces	Requirements for security officers will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces Operations	a) Must have in-service training program. b) Must have Use of Force Continuum. c) Must have communication systems available (i.e., landline on post, cell phones, handheld radio, and desktop computer). d) Must have Standing Post Orders. e) Must wear distinct uniform identifying them as security officers.
5. Security Operations Description:	
Information Sharing	a) Establish formal liaison with law enforcement.

	b) Meet in person at a minimum annually. Document meeting notes and keep them on file for a, minimum of 12 months. POC information for LE Officer that attended the meeting must be documented. c) Implement procedures for receiving and disseminating threat information.
Training	a) Conduct new employee security awareness training. b) Conduct and maintain records of annual security awareness training.
Security Management	a) Designate a knowledgeable security professional to manage the security of the facility. b) Ensure subcontractor compliance with all Government security requirements.
6. Personnel Security Description:	
Records Checks	Verification of social security number, date of birth, citizenship, education credentials, five-year previous employment history, five-year previous residence history, FDA disbarment, sex offender registry, credit check based upon position within the company; motor vehicle records check as appropriate; and local/national criminal history search.
Hiring and Retention Standards	a) Detailed policies and procedures concerning hiring and retention of employees, employee conduct, and off boarding procedures. b) Off Boarding procedures should be accomplished within 24 hour of employee leaving the company. This includes termination of all network access.
7. Information Security Description:	
Physical Document Control	a) Applicable documents shall be identified and marked as procurement sensitive, proprietary, or with appropriate government markings. b) Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet/desk or other storage device and not be left unattended. c) Access to sensitive information should be restricted to those with a need to know.
Document Destruction	Documents must be destroyed using approved destruction measures (i.e, shredders/approved third party vendors / pulverizing / incinerating).
8. Information Technology & Cybersecurity Description:	
Identity Management	a) Physical devices and systems within the organization are inventoried and accounted for annually. b) Organizational cybersecurity policy is established and communicated. c) Asset vulnerabilities are identified and documented. d) Cyber threat intelligence is received from information sharing forums and sources. e) Threats, vulnerabilities, likelihoods, and impacts are used to determine risk.

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

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

ARTICLE 9. Most Favored Customer

A. In the event that the Parties agree to a follow-on production pursuant to 10 U.S.C. § 2371b, Awardee agrees that it shall sell to the U.S. Government the first million doses of AZD7442 at a price of (b) (4) . Any additional doses will be sold to the U.S. Government at a price to be negotiated and agreed by the Parties.

B. If Awardee develops a like product (commercialized version or derivative of the production model of the Prototype) with similar capability and intended application, but at a lower unit price ("Like Product") regardless of quantity, Awardee shall make the U.S. Government aware of that similar product and the technical and price differences between that product and the Prototype. Such notification shall be made to the OTAO in writing, of which email is an acceptable form, within (b) (4) of such offering.

ARTICLE 10. Confidential 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 Agreements Officer and the Awardee may, by mutual consent, identify elsewhere in this Agreement specific information and/or categories of information which the Government will furnish to the Awardee or that the Awardee is expected to generate which is confidential. Similarly, the Agreements Officer and the Awardee 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 Agreement that information to be utilized under this Agreement, or a portion thereof, is subject to the Privacy Act, the Awardee 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 Awardee is uncertain with regard to the proper handling of material under the Agreement, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Awardee shall obtain a written determination from the Agreements Officer prior to any release, disclosure, dissemination, or publication.

F. Agreements Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.

G. The provisions 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 10 flows down to the relevant sub-agreement, and such entity agrees to be in substantial compliance with this Article 10.

ARTICLE 11. Intellectual Property Rights

A. Limited Representation. AstraZeneca represents that, to its knowledge, the intellectual property license(s) and other rights held by or granted to AstraZeneca, including but not limited to those under the Vanderbilt University License Agreement with respect to AZD7442 (AZD1061 + AZD8895) and the University of Texas System license (on behalf of University of Texas Southwestern Medical Center) with respect to AZD7442 (AZD1061 + AZD8895), are sufficient to enable Astra Zeneca to perform its obligations under this Agreement.

B. Background IP and Materials. The Awardee and the Government each retain any intellectual property (IP) rights to their own materials, technical data (as defined in 22 C.F.R. § 120.10), technology, information, documents, or know-how—or potential rights, such as issued patents, patent applications, invention disclosures, copyrighted works, or other written documentation—that exist prior to execution of this Agreement or are developed outside the scope of this Agreement ("Background IP").

C. Awardee's Background IP. Awardee warrants that it (or its upstream licensor) has filed patent application(s) or is the assignee of issued patent(s) identified and listed in Appendix E which contain claims that are related to research contemplated under this Agreement. The Background IP identified and listed in Appendix E is specifically excluded from the definitions of "Agreement Invention" contained in this Agreement. The Government acknowledges that the Awardee will continue to perform research and development efforts in respect of AZD7422, including formulation and delivery work, and improvements to the TM mutation, which work is outside the scope and funding terms of this Agreement and, as a result, any intellectual property generated by the Awardee in the performance of such work constitutes Background IP.

Awardee acknowledges that the Government has funded a subset Awardee's Background IP under the Vanderbilt University License Agreement with respect to AZD7442 (AZD1061+AZD8895) (the "Vanderbilt Agreement"). Furthermore, on November 21, 2017, Agreement HR0011-18-3-001 entitled, "Technology Investment Agreement between MedImmune, LLC and The Defense Advanced Research Projects Agency," was executed with the overall goal of developing an end to end process to identify a novel monoclonal antibody and deliver this antibody using in vivo expression technologies (the "DARPA Agreement"). On December 19, 2017, a Cooperative Agreement, HR0011-18-2-001, was executed between Defense Advanced Research Projects Agency ("DARPA") and Vanderbilt University Medical Center to fund research related to "RRADD: Rational and Rapid Ab Design and Delivery" (together with the Vanderbilt Agreement and the DARPA Agreement, the "Pre-Existing Agreements") DARPA and BARDA established an MOU to cooperative fund an effort to complete R&D, preclinical, and early clinical development of monoclonal antibodies targeting SARS-CoV-2.

D. Government's Background IP. The Government is not providing any Background IP under this Agreement and therefore lists "None" in Appendix E.

E. Agreement Inventions. In the unlikely event that an invention is conceived or first actually reduced to practice in the performance of this Agreement ("Agreement Invention"), ownership of any Agreement Invention, regardless of whether it is not patentable, or is patentable under U.S. patent law that is conceived or first reduced to practice under this Agreement will follow inventorship in accordance with U.S. patent law. Neither the Government nor Awardee anticipate the conception or reduction to practice of any Agreement Invention. The Government acknowledges that in the absence of any Agreement Invention, the Bayh-Dole Act, (35 U.S.C. §§ 200-212) does not apply, nor govern, this Agreement. Since, in the absence of any Agreement Invention, the Bayh-Dole Act, does not apply to this Agreement, as such, title to Agreement Inventions will accrue to the inventor or inventor-organization. In the absence of any Agreement Invention, the Government shall not have any rights to "march-in," as that term is defined in 35 U.S.C. §

203, and Awardee is not subject to the manufacturing requirements of 35 U.S.C. § 204.

In the event an Agreement Invention exists, the Parties represent and warrant that each inventor will assign his or her rights in any such inventions to his or her employing organization. If an Agreement Invention is made either by an Awardee employee ("Sole Awardee Agreement Invention") or made by a Government employee ("Sole Government Agreement Invention") the entire rights to that sole Awardee Agreement Invention or Sole Government Agreement Invention will be respectively assigned to the Awardee or the Government. If an Awardee employee and a Government employee jointly make an Agreement Invention ("Joint Agreement Invention"), it will be owned jointly by the Awardee and the Government. Ownership of inventions made in whole or in part with Sub-awardee or collaborator employees, including employees of other components of the Government, will be determined solely pursuant to an agreement between the Awardee and the applicable Sub-awardee or collaborator. Notwithstanding the foregoing, neither the Government nor Awardee anticipate the Government making a Sole Government Agreement Invention, nor the Parties jointly making a Joint Agreement Invention, as Awardee employees are solely responsible, as between the Parties, for performing the Prototype Project under this Agreement.

F. Patent Applications. Each Party shall disclose any Agreement Inventions for which the Party plans to file a patent application within (b) (4) of the time it was conceived or first reduced to practice under this Agreement. The Parties will respectively have the option, in their discretion, to file a patent application claiming any Agreement Invention made solely by their respective employees (but, for clarity, are not obligated to file a patent application claiming any Agreement Invention, and will not forfeit title by electing to hold an Agreement Invention as a trade secret). The Parties will consult with each other regarding the options for filing a patent application claiming a Joint Agreement Invention. Within one (1) year of being notified of the discovery of an Agreement Invention for which a patent application is planned, each Party will provide notice of any filing of a patent application to the other Party. The Parties will reasonably cooperate with each other in the preparation, filing, and prosecution of any patent application claiming a Joint Agreement Invention. Any Party filing a patent application will bear expenses associated with filing and prosecuting the application, as well as maintaining any patents that issue from the application, unless otherwise agreed by the Parties. Executive Order No. 9424 of 18 February 1944 requires all executive Departments and agencies of the Government to forward through appropriate channels to the Commissioner of Patents and Trademarks, for recording, all Government interests in patents or applications for patents.

G. Patent Prosecution. Awardee agrees to take responsibility for the preparation, filing, prosecution, and maintenance of any and all patents and patent applications listed as Awardee Background IP that are relevant to the work performed under this Agreement. Awardee shall keep the Government reasonably advised on the status of Awardee Background IP by providing an annual report on the status of Awardee Background IP. With respect to any Sole Awardee Agreement Invention or a Joint Agreement Invention, prior to acting on a decision by Awardee to abandon or not file in any country a patent or patent application covering an Sole Awardee Agreement Invention or a Joint Agreement Invention, Awardee shall so inform the Government in a timely manner to allow Awardee to thoughtfully consider the Government's comments regarding such a proposed decision. Nothing in this ARTICLE shall restrict the Government in its preparation, filing, prosecution and maintenance of a patent or patent application covering an Agreement Invention.

H. Licenses.

i. Background IP. The Awardee acknowledges the Government's pre-existing rights in Background IP generated in the performance of the Pre-Existing Agreements, and nothing in this Agreement is intended to alter any rights the Government may have in Background IP generated in performance thereof. For clarity, the Awardee does not grant to the Government any license or right to use any of the Background IP identified in Appendix E which was not generated in the performance of a

Government funding agreement.

ii. Agreement Inventions. Any Sole Awardee Agreement Invention is subject to a nonexclusive, nontransferable, irrevocable, paid-up license for the Government, to practice and have practiced the Agreement Invention on behalf of the Government. For any Sole Government Agreement Invention, upon the Recipient's request, the Government agrees to enter into good faith negotiations with the Recipient regarding the Recipient's receipt of a nonexclusive commercialization license covering the Government's interest in any Sole Government Agreement Invention.

ARTICLE 12. Data Rights

A. Background Data. "Background Data" shall mean all technical data, as the term is defined in DFARS 252.227-7013 (a) (15), that exists prior to execution of this Agreement, or are developed outside the scope of this Agreement. Awardee warrants that it has identified and listed Background Data in Appendix F. The Parties acknowledge and agree that: (i) the Government has been granted rights to certain technical data that are independent of this Agreement, and may be disclosed in Awardee's Background Data listed in Appendix F; and (ii) the Government's rights in said technical data are not superseded or otherwise reduced by this Agreement.

All Background Data shall be owned by the Awardee. AstraZeneca grants the Government a non-exclusive license to use any Background Data solely to the extent necessary for the Government to perform its obligations under this Agreement and arrange administration of treatment courses delivered in accordance with FDA and other applicable regulations.

As used herein, "Limited Rights" means, in respect of any technical data, the rights to use, modify, reproduce, perform, display, or disclose data, in whole or in part, within the Government solely for research purposes in respect of the prophylaxis and treatment of COVID-19. The Government will ensure that disclosed information is safeguarded in accordance with the restrictions of this Agreement. The Government may not, without the prior written permission of the Awardee, release or disclose the data outside the Government, use the data for competitive procurement or manufacture, release or disclose the data for commercial purposes, or authorize the data to be used by another party. The Parties shall maintain the confidentiality of all data subject to or designated as falling within Limited Rights.

As used herein, "Government Purpose Rights" means the rights to (i) use, modify, reproduce, release, perform, display, or disclose data solely within the Government, (ii) release or disclose data outside the Government, and (iii) authorize persons to whom release or disclosure has been made to use, modify, reproduce, release, perform, display, or disclose that data; in each case (i)-(iii) solely as required for Government purposes. Government purposes do not include the rights to use, modify, reproduce, release, perform, display, or disclose data for commercial or competitive purposes or to authorize others to do so. Even where disclosure is made for Government purposes, such disclosure will be governed by a contractual terminology or a non-disclosure agreement restricting further dissemination of the information and otherwise ensuring compliance with the government's rights and obligations in the disclosed data.

B. Subject Data. All data generated in connection with the performance of this Agreement, or that arises out of the use of any materials or enabling technology provided or used by the Awardee in the performance of this Agreement, other Awardee materials or Awardee confidential information, whether conducted by the Government or the Awardee (collectively, the "Subject Data"), shall be owned by the Awardee.

Subject Data in any document that would disclose an Agreement Invention will be subject to Limited Rights until publication of patent application in accordance with Article 11 of this Agreement.

The Awardee agrees to retain and maintain all Subject Data (i) in a clear and readable manner, such that the Government reasonably could use such Subject Data in connection with its rights under Article 18 and (ii) in accordance with the Awardee's established record retention practices. In the event of exercise of the Government's rights as potentially granted under Article 2, paragraph C, the Awardee agrees to deliver at no additional cost to the Government, all Subject Data, in Awardee's possession and developed under this Agreement, necessary for the Government to exercise its rights under Article 18within sixty (60) calendar days from the date of the written request. The Government shall retain Limited Rights, as defined in Article I above, to this delivered Subject Data.

C. Marking of Data. Pursuant to paragraph A above, the Awardee will use reasonable efforts to mark any Data delivered to the Government under this Agreement with Limited Rights with the following legend:

"LIMITED RIGHTS" The Government's right to use, modify, reproduce, perform, display, or disclose this Data is restricted by Agreement W911QY-21-9-0001 between the Government and the Awardee (disclosure is limited within the Government). Any reproduction of this Data or portions thereof marked with this legend must also reproduce the markings."

Notwithstanding the foregoing, in the event the Government receives Background Data or Subject Data delivered under this Agreement that is not marked with the foregoing legend the Government shall treat such information as if it were marked with the foregoing legend.

D. All Technical Data and Software (each term as defined under DFARS 252.227-7013) which shall be delivered under this Agreement with less than unlimited rights shall be identified in reasonable specificity and particular rights granted (Government Purpose (as defined in this Agreement), Limited (as defined in this Agreement), or Restricted (as defined in DFARS 252.227-7013)) prior to entering into the Agreement. All other Technical Data and Software developed under funding of this agreement shall be delivered with Limited Rights as provided for within this Article.

ARTICLE 13. Regulatory Rights

A. This Agreement involves research with an investigational drug, biologic or medical device that is regulated by the FDA and requires FDA pre-market approval or licensure before commercial authorization. It is expected that this contract will result in the FDA authorization, licensure, and commercialization of the "Technology. The Awardee is the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), emergency use authorization (EUA), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) that controls research under this contract. As the Sponsor of the Regulatory Application to FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), the Awardee has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

B. The Parties agree that Awardee 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 Awardee and the Government agree to the following:

i. The Awardee 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 Awardee 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 Awardee 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 Awardee will keep the Government apprised of planned FDA meetings and post-meeting outcomes relating to activities funded by this Agreement.

ii. Communications. The Awardee 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. Awardee 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.

iii. Public Law 115-92 Sponsor Authorization Letter. Public Law 115-92 allows the DoD to request, and FDA to provide, assistance to expedite development of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. The Awardee recognizes that only the DoD can utilize PL 115-92. As such, the Awardee will work proactively with the Government to leverage this law to its maximum potential under this Agreement. The Awardee shall submit Public Law 115-92 Sponsor Authorization Letter that will be delivered to the designated OWS POC(s) within (b (b) of award. For clarity, any information delivered to the Government pursuant to the Sponsor Authorization Letter shall be subject to the Data Rights in Article 8.

iv. Rights of Reference. Awardee hereby grants to the Government and its permitted sublicensees the right to request from Recipient, which request shall not be unreasonably declined or delayed, a limited "right of reference or use" (as that term is defined in 21 C.F.R. § 314.3(b), as amended from time to time) strictly for COVID-19 or other Material Threat (as defined at Section 319 of the Public Health Service Act) Purposes to Awardee's filings to the FDA in connection with the Regulatory Application, and Awardee shall provide appropriate notification of the Government's access and reference rights to the applicable regulatory authorities requested by the Government for the limited purposes described above. Awardee agrees to provide a letter of cross-reference to the Government and file such letter with the appropriate FDA office. The USG will agree to any reasonable request for information connected to its reliance on the right of reference provided under this Section. This provision is in addition to any rights in technical data described earlier in this document.

ARTICLE 14. Regulatory Compliance.

A. 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.

B. 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.

C. The clinical trial described in the Statement of Work will comply with ICH Good Clinical Practices (GCP) regulations at 21 CFR Part 11.

D. All clinical sites and IRBs utilized in the clinical trial described in the Statement of Work are required to register with the Office for Human Research Protections (OHRP) and receive Federal Wide Assurance (FWA) numbers in accordance with human subject protections regulations 45 C.F.R 46.103.

ARTICLE 15. Foreign Access to Data.

A. Export Compliance. The Parties will comply with any applicable U.S. export control statutes or regulations in performing this Agreement.

ARTICLE 16. Scientific Publications and Press Releases.

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

B. Unless otherwise specified in this Agreement, the Awardee may publish the results of its work under this Agreement. The Awardee shall promptly send a copy of each submission to the AOR for security review prior to submission, and the Government's consent shall not be unreasonably withheld or delayed (and in no event by more than (b) (4)). The Awardee shall also inform the AOR when the abstract article or other publication is published, and furnish a copy of it as finally published.

C. Unless authorized in writing by the AO, the Awardee shall not display Government logos including Operating Division or Staff Division logos on any publications.

D. The Awardee 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.

E. The Awardee shall include this clause, including this section (d) in all subawards where the subawardee may propose publishing the results of its work under the subaward. The Awardee shall acknowledge the support of the Government whenever publicizing the work under this Agreement 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 Agreement No. W911QY-21-9-0001. The US Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon."

ARTICLE 17. Immunity from Liability.

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

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

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

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

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

The Government may not use, or authorize the use of, any products or materials provided under this Agreement, unless such use occurs in the United States (or a U.S. territory where U.S. law applies including, but not limited to, embassies, military installations and NATO installations) and is protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act Declaration of equal or greater scope. Any use where the application of the PREP Act is in question will be discussed with AstraZeneca prior to use and, if the Parties disagree on such use, the dispute will be resolved according to Article 5(H).

ARTICLE 18. Ensuring Sufficient Supply of the Product

A. In recognition of the Government's significant funding for the development and manufacturing of the Technology and the Government's need to provide sufficient quantities of a COVID-19 treatment to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the Technology to meet the needs of the public health or national security. This remedy is not available to the Government unless and until any of the following conditions is met, and is not available as a result of a termination under Article 2.B of this Agreement:

i. Awardee gives notice to the Government of any formal management decision to terminate the product development effort before all milestones in this Agreement are satisfied, including but not limited to delivery of (b) (4) of AZD7442 (which notice, for clarity, must be provided no later than (b) (4) after the date of such formal management decision);

ii. Within twenty-four (24) months after the effective date of this Agreement, Awardee, or another entity acting on Awardee's behalf, fails to obtain either an Emergency Use Authorization under §564 of the FD&C Act or a biologics license application under the provisions of §351(a) of the Public Health Service Act (PHSA) to permit use and marketing of the Technology;

iii. Awardee fails to commercially market or provide an acceptable life cycle plan for continued supply of the Technology within one (1) year after FDA approval, licensure or clearance;

iv. AstraZeneca gives written notice, required to be submitted to the Government no later than 15

business days, of any filing that anticipates Federal bankruptcy protection; or

v. The Government terminates this agreement for cause in accordance with Article 2(C).

B. If one or more of the conditions listed in section (A) occur, AstraZeneca, upon the request of the Government, shall provide the following items necessary for the Government to pursue FDA licensure/authorization and manufacturing of the Technology with a third party for exclusive sale to the U.S. Government:

i. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any AstraZeneca Background IP and Background Data, as those terms are defined in Articles 11 and 12 of this Agreement, necessary to manufacture or have manufactured the Technology;

ii. necessary FDA regulatory filings or authorizations owned or controlled by AstraZeneca related to the Technology and any confirmatory instrument pertaining thereto; and

iii. any outstanding Deliverables contemplated or materials purchased under this Agreement.

C. The Government acknowledges that, under the Awardee's pre-existing agreement with its upstream licensor, Vanderbilt University, if (i) the Awardee fails to use commercially reasonable efforts to bring AZD7442 to market, or (ii) fails to file for approval of a BLA or an EUA by (b) (4) the upstream licensor has the right to obtain licenses and technology transfer from the Awardee such that the upstream licensor is able to commercialize AZD7442 in the United States.

Awardee shall notify the Government within 30 days if Awardee becomes aware that the upstream licensor intends or has threatened to exercise its rights to obtain licenses and technology transfer from Awardee. If the upstream licensor exercises this right, Awardee shall so notify the Government within 30 days, and the Government agrees that it will not exercise its rights in the foregoing Section 18.B without prior consent from Vanderbilt. If the upstream licensor notifies the Awardee that it declines to commercialize AZD7442 in the United States, the Awardee will notify the Government within thirty (30) days after receipt of such notice, in which case the Government may elect to exercise its rights under the foregoing Section 18.B. If the Government, or any third party designated by the Government, obtains any such license or sublicense from the Awardee, the Government, or any such designated third party, shall be solely liable for all royalties, costs and other expenses incurred by the Awardee and payable to a third party in consideration for such license or sublicense (including, but not limited to, payment obligations the Awardee has to its upstream licensor for AZD7442).

D. The Awardee acknowledges that a scenario may arise in which the Awardee terminates product development efforts and gives notice to the Government as provided in Section 18.A(i), but that such termination does not constitute a violation of the Awardee's "commercially reasonable efforts" obligation to Vanderbilt, and therefore does not trigger Vanderbilt's rights to exercise step-in rights as described in Section 18.C. The Awardee acknowledges that, in such a scenario, the Government may continue to exercise its rights as set forth in Section 18.B.

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

ARTICLE 19. Miscellaneous Clauses.

A. Patent Infringement. Each Party will advise the other Party promptly and in reasonable written detail, of each claim or lawsuit of patent infringement based on the performance of this Agreement. When requested by either Party, all evidence and information in possession of the Party pertaining to such claim or lawsuit will be provided to the other at no cost to the requesting Party.

B. Limitation of Liability. Except for claims of non-payment of amounts due under Article 7, any claims for damages of any nature whatsoever pursued under this Agreement shall be limited to direct damages only up to the aggregate amount of Government funding disbursed as of the time the dispute arises. In no event will either Party be liable to the other Party or any third party claiming through such Party for any indirect, incidental, consequential or punitive damages, or claims for lost profits, arising under or relating to this Agreement, whether based in contract, tort or otherwise, even if the other Party has been advised of the possibility of such damages.

C. Disclosure of Information. Performance under this Agreement may require the Awardee 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 Awardee, nor Awardee personnel, shall divulge nor release data nor information developed or obtained from or on behalf of the Government under performance of this Agreement which information specifically relates to AZD7442 (*i.e.*, would not apply more broadly to AstraZeneca's other antibody programs, such as its manufacturing platform), except as authorized by Government personnel or upon written approval of the AO in accordance with OWS or other Government policies and/or guidance. The Awardee shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this Agreement, or any information at all regarding this agency.

The Awardee 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 Agreement, replacement of an Awardee employee, or other appropriate redress. Neither the Awardee nor the Awardee'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 Agreement shall be released or publicized without the prior written consent of the AOR, 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 Awardee'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.

D. Force Majeure. Neither Party will be liable to the other Party for failure or delay in performing its obligations hereunder if such failure or delay arises from circumstances beyond the control and without the fault or negligence of the Party (a Force Majeure event). Examples of such circumstances are: authorized acts of the government in either its sovereign or contractual capacity, war, insurrection, freight embargos, fire, flood, or strikes. The Party asserting Force Majeure as an excuse must take reasonable steps to minimize delay or damages caused by unforeseeable events.

E. Severability. If any provision of this Agreement, or the application of any such provision to any

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

F. Choice of Law. This Agreement and the resolution of disputes hereunder will be governed, construed, and interpreted by the statutes, regulations, and/or legal precedent applicable to the Government of the United States of America. Unless explicitly stated, the Parties do not intend that this Agreement be subject to the Federal Acquisition Regulation either directly or indirectly or by operation of law. When a specific FAR requirement is incorporated by reference in this Agreement, the text of the clause alone will apply without application or incorporation of other provisions of these regulations.

G. Order of Precedence. In the event of a conflict between the terms of this Agreement and the attachments incorporated herein, the conflict shall be resolved by giving precedence in descending order as follows: (i) the Articles of this Agreement, and the Appendices to the Agreement.

H. Access and General Protection/Security Policy and Procedures. This standard language text is applicable to ALL employees working on critical information related to OWS 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.

I. Financial Disclosure by Clinical Investigators. The Awardee does and shall comply with the requirements of 21 CFR Part 54, Financial Disclosure by Clinical Investigators.

J. Performance by Affiliates. The Government acknowledges and agrees that the Awardee may perform its obligations under this Agreement through one or more of its affiliates, provided that the Awardee will be responsible for the full and timely performance as and when due under, and observance of, all the covenants, terms, conditions and agreements set forth in this Agreement by its affiliates.

K. Subcontracts.

1. The Government acknowledges that, in order to combat the global pandemic and launch (b) (4) as quickly as possible, Recipient has entered into a number of contracts prior to the Execution Date, and the Government agrees that it will not require these contracts to be renegotiated. Therefore, except as otherwise expressly set forth in this Article 19.K, any provision requiring Recipient to flow-down an obligation to its sub-agreement holders will apply only to sub-agreements executed by Recipient following the Execution Date of this Agreement.

2. For clarity, as detailed within the Articles themselves, the following Articles require flow-down to subagreements/contracts executed after the Execution Date:

(i) Article 10: Confidential Information.

(ii) Article 8.B.11: Security Plan.

(iii) Article 14.d: Requirement to register with the OHRP and receive FWA.

3. Section 19.L will be flowed-down to all subagreements/contracts as set forth in FAR 52.204-25, whether executed before or after the Execution Date.

L. Use of Covered Telecommunications. FAR 52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment is hereby incorporated by reference.

Appendix A
Statement of Work

Overall Objectives and Scope

The overall objective of this contract is to evaluate the clinical efficacy of AZD7442, demonstrate manufacturing capability, and technology transfer manufacturing processes to facilitate increased production scale.

The scope of work is outlined across both clinical and manufacturing efforts necessary to submit a request for an Emergency Use Authorization (EUA) or a Biologics License Application (BLA) following completion of the clinical studies, and includes stockpiling and development of a distribution process capable of delivering AZD7442 to point of care facilities.

The items outlined are based on current plans and are subject to change as the development plan progresses, regulatory input is received on the program and funding allocations are agreed upon.

1.0 Technical and Program Management

AstraZeneca will provide for the overall management, integration and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation and direction of all contract activities to support the timely delivery of all deliverables required under the contract.

AstraZeneca will develop an integrated master schedule, track milestone progress and develop a risk management plan to ensure accurate reporting and milestone delivery.

2.0 Clinical Studies

AstraZeneca plans to conduct two pivotal clinical studies to evaluate the efficacy of AZD7442.

(b) (4)

[redacted]

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							

(b) (4)

[redacted]

(b) (4)

[redacted]

Appendix C
Key Personnel

1. Awardee's Organization and Key Personnel.

The Awardee'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 Agreement and its integrity shall be maintained for the duration of the effort.

The key personnel listed below are considered to be critical to the successful performance of this Agreement. Prior to replacing these key personnel, the Awardee shall obtain the written consent of the AO. In order to obtain such consent, the Awardee shall provide advance notice of the proposed changes and shall demonstrate that the qualifications of the proposed substitute personnel are generally equivalent to or better than the qualifications of the personnel being replaced.

The Awardee 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 Appendix. 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 Agreements Officer or authorized representative will evaluate such requests and promptly notify the Awardee of approval or disapproval thereof.

The Awardee further agrees to include the substance of this clause in any subcontract, which may be awarded under this Agreement.

Prior to permanently removing any of the specified individuals to other contracts, the Awardee shall provide the AO not less than thirty (30) calendar days advance notice and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. If the employee of the Awardee is terminated for cause or separates from the Awardee voluntarily with less than thirty (30) calendar-day notice, the Awardee 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 Agreements Officer. The "Key Personnel" list presented in Table 2 below may be amended from time to time during the course of the Agreement to either add or delete personnel, as appropriate.

Name	Role
(b) (6)	

(b) (6) [redacted]

Appendix D
Government Property

Government Property: **"**Government Property" means any property (i) furnished by the Government and facilitating performance of this Agreement, (ii) acquired by the Awardee under cost reimbursement terms of this Agreement, or (iii) acquired by the Awardee under fixed price terms of this Agreement (FP-GP) if specifically identified in this Government Property Appendix. Except for commercial off the shelf software and licenses thereto, Government Property does not include intellectual property and software. The Government owns and holds title to all Government Property.

The Government shall deliver to the Awardee any Government Property required to be furnished as described in this Agreement together with related data and information needed for its intended use. The delivery and/or performance dates specified in this Agreement are based upon the expectation that the Government-furnished property will be suitable for performance and will be delivered to the Awardee by the dates stated in the Agreement. If not so suitable, the Awardee shall give timely written request to the AO who will advise the Awardee on a course of action to remedy the problem.

FPGP includes: [Mark N/A if none]:

N/A

The Awardee shall have, initiate and maintain a system of internal controls to manage, control, use, preserve, protect, repair, account for and maintain Government Property in its possession and shall initiate and maintain the processes, systems, procedures, records required control and maintain accountability of Government Property. The Awardee shall include this clause in all subcontracts under which Government Property comes into the possession of any subawardee. Unless otherwise provided for in this Agreement or approved by the AO, the Awardee shall not: (i) use Government Property for any purpose other than to fulfill the requirements of this Agreement, or (ii) alter the Government Property.
The Awardee shall establish and implement property management plans, systems, and procedures regarding its acquisition of Government Property, its receipt of Government Property, in addition to, the status, dates furnished or acquired, identification, quantity, cost, marking, date placed in service, location, inventory and disposition of Government Property, to include a reporting process for all discrepancies, loss of Government Property, physical inventory results, audits and self-assessments, corrective actions, and other property related reports as directed by the AO.

Upon conclusion or termination of the Agreement, the Awardee shall submit a request in writing to the AO, for disposition/disposal instructions and shall store Government Property not to exceed 120 days pending receipt of such instructions. Storage shall be at no additional cost to the Government unless otherwise noted in the Agreement. The Government, upon written notice to the Awardee, may abandon any Government Property in place, at which time all obligations of the Government regarding such Government Property shall cease.

Awardee Liability for Government Property. "Loss of Government Property" means the loss, damage or destruction to Government Property reducing the Government's expected economic benefits of the property and includes loss of accountability but does not include planned and purposeful destructive testing, obsolescence, reasonable wear and tear or manufacturing defects. THE AWARDEE SHALL BE LIABLE FOR LOSS OF GOVERNMENT PROPERTY IN AWARDEE'S POSSESSION, EXCEPT WHEN ANY ONE OF THE FOLLOWING APPLIES:

(I) AO GRANTS RELIEF OF RESPONSIBILITY AND LIABILITY FOR LOSS OF THE PARTICULAR GOVERNMENT PROPERTY; (II) GOVERNMENT PROPERTY IS DELIVERED OR SHIPPED UNDER THE GOVERNMENT'S INSTRUCTIONS; OR (III) GOVERNMENT PROPERTY IS DISPOSED OF IN ACCORDANCE WITH THE GOVERNMENT'S DIRECTIONS.

Appendix E
Background IP

Government Background IP: None

AstraZeneca Background IP:

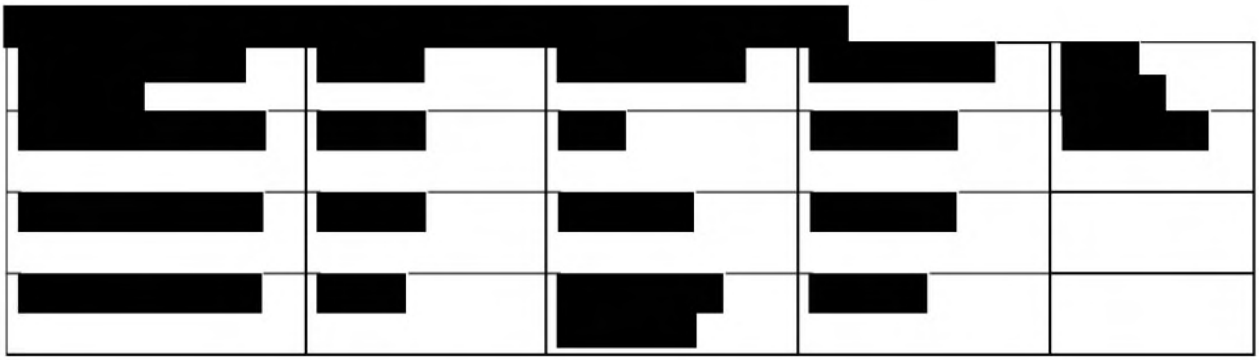
(b) (4)

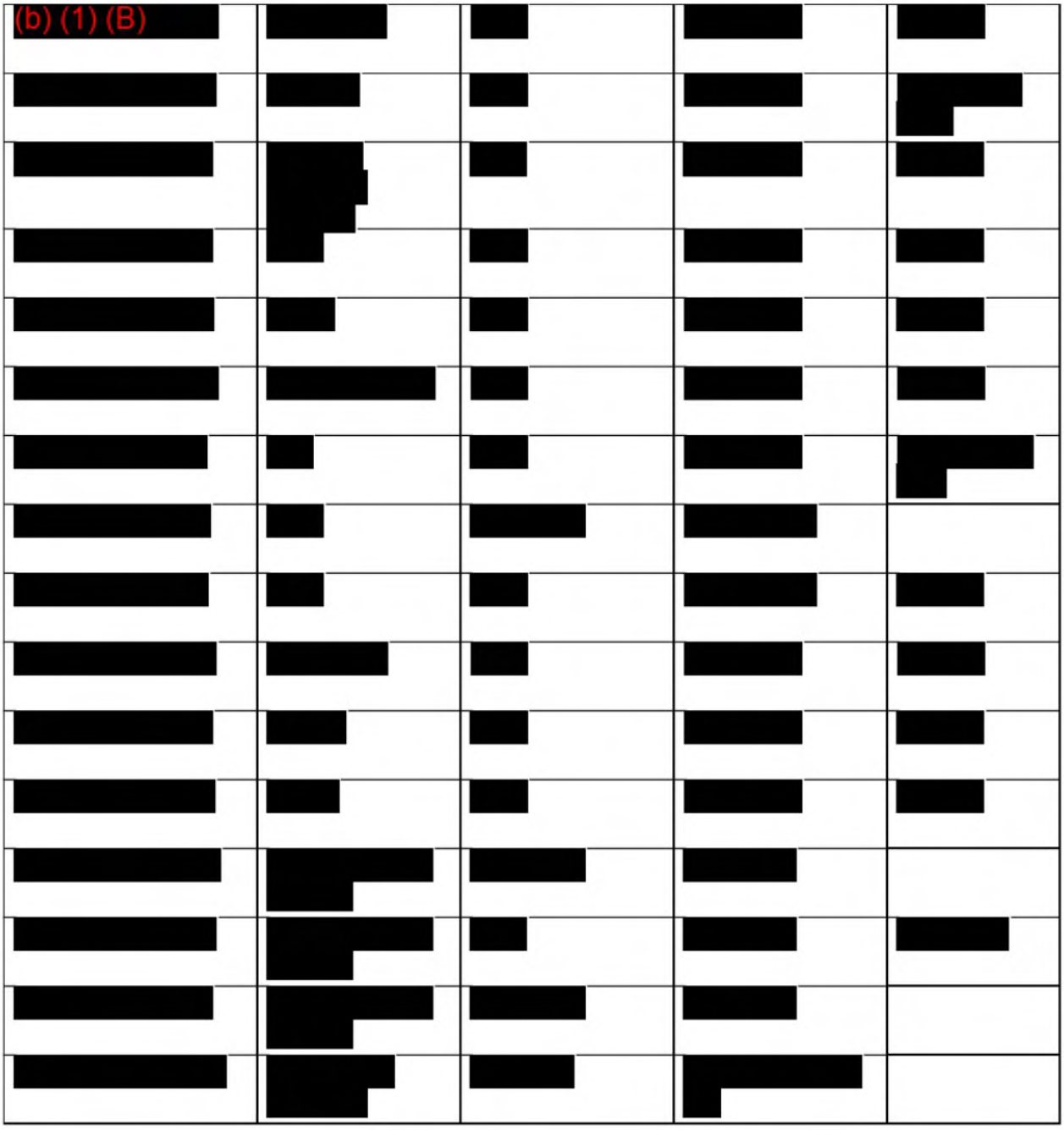
[redacted]

(b) (4)


(b) (4)


(b) (4)




(b) (1) (B)

AWARD/CONTRACT

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES
		1 | 33

2. CONTRACT (Proc. Inst. Ident.) NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
W911QY2190001	09 Oct 2020	0011560606

5. ISSUED BY	CODE	6. ADMINISTERED BY (If other than Item 5)	CODE
W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK DIVISION 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and zip code)	8. DELIVERY	ITEM
ASTRAZENECA PHARMACEUTICALS LP 1800 CONCORD PIKE WILMINGTON DE 19803-2902	[ ] FOB ORIGIN [X] OTHER (See below) 9. DISCOUNT FOR PROMPT PAYMENT 10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN:	

CODE 36WK2	FACILITY CODE

11. SHIP TO/MARK FOR	CODE	12. PAYMENT WILL BE MADE BY	CODE
See Schedule		DEFENSE FINANCE AND ACCOUNTING SERVICE DFAS-INDY VP GFEBS 8899 E 56TH STREET INDIANAPOLIS IN 46249-3800	HQ0490

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:	14. ACCOUNTING AND APPROPRIATION DATA
[ ] 10 U.S.C. 2304(c)( ) [ ] 41 U.S.C. 253(c)( )	See Schedule

15A. ITEM NO.	15B. SUPPLIES/ SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	SEE SCHEDULE				

15G. TOTAL AMOUNT OF CONTRACT (b) (4)

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				**PART II - CONTRACT CLAUSES**	
X	A	SOLICITATION/ CONTRACT FORM	1	X	I	CONTRACT CLAUSES	33
X	B	SUPPLIES OR SERVICES AND PRICES/ COSTS	2 - 22			**PART III – LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.**	
	C	DESCRIPTION/ SPECS/ WORK STATEMENT			J	LIST OF ATTACHMENTS	
	D	PACKAGING AND MARKING				**PART IV - REPRESENTATIONS AND INSTRUCTIONS**	
X	E	INSPECTION AND ACCEPTANCE	23 - 24		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	25 - 27				
X	G	CONTRACT ADMINISTRATION DATA	28 - 32		L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
	H	SPECIAL CONTRACT REQUIREMENTS			M	EVALUATION FACTORS FOR AWARD	

CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. [ ] CONTRACTOR'S NEGOTIATED AGREEMENT Contractor is required to sign this document and return copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)

18. [ ] SEALED-BID AWARD (Contractor is not required to sign this document.)
Your bid on Solicitation Number _____
including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the terms listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER (Type or print)	20A. NAME OF CONTRACTING OFFICER
	(b) (6) / CONTRACTING OFFICER TEL: (b) (6) EMAIL: (b) (6)

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
BY _____ (Signature of person authorized to sign)		BY (b) (6) (Signature of Contracting Officer)	09-Oct-2020

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001		1	Each	(b) (4)	(b) (4)

MS 1 Security and Supply Planning
FFP
Security Plan, Supply Chain Resilieny Plan, Manufacturing Data Requirements, Product Material Source Report and Quality Agreement in accordance with the terms of the agreement.
FOB: Destination
PSC CD: AN14

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000101					(b) (4)

Funding
FFP
PURCHASE REQUEST NUMBER: 0011560606

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156060600001

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002		1	Each	(b) (4)	(b) (4)

MS2 Operational Security Standard OP
FFP
MS 2 Operational Security SOP in accordance with the terms of the agrement.
FOB: Destination
PSC CD: AN14

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000201					(b) (4)

Funding
FFP
PURCHASE REQUEST NUMBER: 0011560606

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156060600002

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003		1	Each	(b) (4)	(b) (4)

MS 3 Contract Closeout
FFP
MS 3 Contract Summary Report in accordance with the terms of the agreement.
FOB: Destination
PSC CD: AN14

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000301					(b) (4)

Funding
FFP
PURCHASE REQUEST NUMBER: 0011560606

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156060600003

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0004		1	Each	(b) (4)	(b) (4)

MS 4 Provent-Enabling Activities
FFP
MS 4 Clinical Study Protocol & IB in accordance with the terms of the agreement.
FOB: Destination
PSC CD: AN14

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000401					(b) (4)

Funding
FFP
PURCHASE REQUEST NUMBER: 0011560606

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156060600004

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0005		1	Each	(b) (4)	(b) (4)

MS 5 Provent-Dosing
FFP
MS 5 Provent Dosing in accordance with the terms of the agreement.
FOB: Destination
PSC CD: AN14

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000501					(b) (4)

Funding
FFP
PURCHASE REQUEST NUMBER: 0011560606

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156060600005

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0006		1	Each	(b) (4)	(b) (4)

MS 6 Provent-Efficacy Results
FFP
MS 6 Provent-Efficacy Results in accordance with the terms of the agreement.
FOB: Destination
PSC CD: AN14

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000601					(b) (4)

Funding
FFP
PURCHASE REQUEST NUMBER: 0011560606

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156060600006

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0007		1	Each	(b) (4)	(b) (4)

MS 7 Provent-Completion
FFP
MS 7 Provent-Completion in accordance with the terms of the agreement.
FOB: Destination
PSC CD: AN14

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000701					(b) (4)

Funding
FFP
PURCHASE REQUEST NUMBER: 0011560606

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156060600007

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0008		1	Each	(b) (4)	(b) (4)

MS 8 StormChaser-Enabling Activities
FFP
MS 8 StormChaser-Enabling Activities in accordance with the terms of the agreement.
FOB: Destination
PSC CD: AN14

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000801					(b) (4)

Funding
FFP
PURCHASE REQUEST NUMBER: 0011560606

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156060600008

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0009		1	Each	(b) (4)	(b) (4)

MS 9 StormChaser-Dosing
FFP
MS 9 StormChaser-Dosing in accordance with the terms of the agreement.
FOB: Destination
PSC CD: AN14

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000901					(b) (4)

Funding
FFP
PURCHASE REQUEST NUMBER: 0011560606

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156060600009

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0010		1	Each	(b) (4)	(b) (4)

MS 10 StormChaser-Efficacy Results
FFP
MS 10 StormChaser-Efficacy Results in accordance with the terms of the agrement.
FOB: Destination
PSC CD: AN14

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
001001					(b) (4)

Funding
FFP
PURCHASE REQUEST NUMBER: 0011560606

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156060600010

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0011		1	Each	(b) (4)	(b) (4)

MS 11 StormChaser-Completion
FFP
MS 11 StormChaser-Completion in accordance with the terms of the agreement.
FOB: Destination
PSC CD: AN14

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
001101					(b) (4)

Funding
FFP
PURCHASE REQUEST NUMBER: 0011560606

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156060600011

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0012		(b	Job	(b) (4)	(b) (4)

MS 12 StormChaser-Mobile Units
COST
MS 12 StormChaser-Mobile Units in accordance with the terms of the agreement.
FOB: Destination
PSC CD: AN14

ESTIMATED COST (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
001201					(b) (4)

Funding
COST
PURCHASE REQUEST NUMBER: 0011560606

ESTIMATED COST (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156060600012

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0013		1	Each	(b) (4)	(b) (4)

MS 13 Mfg. Capability-Batch 1 Mfg
FFP
MS 13 Mfg. Capability-Batch 1 Mfg in accordance with the terms of the agreement.
FOB: Destination
PSC CD: AN14

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
001301					(b) (4)

Funding
FFP
PURCHASE REQUEST NUMBER: 0011560606

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156060600013

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0014		1	Each	(b) (4)	(b) (4)

MS 14 Mfg. Capability-Batch 2 Mfg
FFP
MS 14 Mfg. Capability-Batch 2 Mfg in accordance with the terms of the agreement.
FOB: Destination
PSC CD: AN14

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
001401					(b) (4)

Funding
FFP
PURCHASE REQUEST NUMBER: 0011560606

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156060600014

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0015		1	Each	(b) (4)	(b) (4)

MS 15 Mfg. Capability-Batch 3 Mfg
FFP
MS 15 Mfg. Capability-Batch 3 Mfg in accordance with the terms of the agreement.
FOB: Destination
PSC CD: AN14

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
001501					(b) (4)

Funding
FFP
PURCHASE REQUEST NUMBER: 0011560606

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156060600015

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0016		1	Each	(b) (4)	(b) (4)

MS 16 Mfg. Capability-Batch 4 Mfg
FFP
MS 16 Mfg. Capability-Batch 4 Mfg in accordance with the terms of the agreement.
FOB: Destination
PSC CD: AN14

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
001601					(b) (4)

Funding
FFP
PURCHASE REQUEST NUMBER: 0011560606

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156060600016

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0017		1	Each	(b) (4)	(b) (4)

MS 17 Mfg. Capability-Batch 5 Mfg.
FFP
MS 17 Mfg. Capability-Batch 5 Mfg in accordance with the terms of the agreement.
FOB: Destination
PSC CD: AN14

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
001701					(b) (4)

Funding
FFP
PURCHASE REQUEST NUMBER: 0011560606

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156060600017

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0018		1	Each	(b) (4)	(b) (4)

MS 18 Mfg. Capability-Batch 6 Mfg.
FFP
MS 18 Mfg. Capability-Batch 6 Mfg in accordance with the terms of the agreement.
FOB: Destination
PSC CD: AN14

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
001801					(b) (4)

Funding
FFP
PURCHASE REQUEST NUMBER: 0011560606

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156060600018

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0019		1	Each	(b) (4)	(b) (4)

MS 19 Mfg. Capability-Batch 7 Mfg
FFP
MS 19 Mfg. Capability-Batch 7 Mfg in accordance with the terms of the agreement.
FOB: Destination
PSC CD: AN14

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
001901					(b) (4)

Funding
FFP
PURCHASE REQUEST NUMBER: 0011560606

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156060600019

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0020		1	Each	(b) (4)	(b) (4)

MS 20 Tech Transfer-(b) (4)
FFP
MS 20 Tech Transfer - (b) (4) in accordance with the terms of the agreement.
FOB: Destination
PSC CD: AN14

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
002001					(b) (4)

Funding
FFP
PURCHASE REQUEST NUMBER: 0011560606

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156060600020

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0021		1	Each	(b) (4)	(b) (4)

MS 21 Tech Transfer-(b) (4)
FFP
MS 21 Tech Transfer - (b) (4) in accordance with the terms of the agreement.
FOB: Destination
PSC CD: AN14

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
002101					(b) (4)

Funding
FFP
PURCHASE REQUEST NUMBER: 0011560606

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156060600021

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0022		1	Each	(b) (4)	(b) (4)

MS 22 Tech Transfer-(b) (4)
FFP
MS 22 Tech Transfer -(b) (4) in accordance with the terms of the agreement.
FOB: Destination
PSC CD: AN14

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
002201					(b) (4)

Funding
FFP
PURCHASE REQUEST NUMBER: 0011560606

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156060600022

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0023		1	Each	(b) (4)	(b) (4)

MS 23 Tech Transfer-(b) (4)
FFP
MS 23 Tech Transfer - (b) (4) in accordance with the terms of the agreement.
FOB: Destination
PSC CD: AN14

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
002301					(b) (4)
	Funding FFP PURCHASE REQUEST NUMBER: 0011560606				
				NET AMT	(b) (4)
	ACRN AA CIN: GFEBS001156060600023				(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0024		1	Each	(b) (4)	(b) (4)
	MS 24 Distribution Setup FFP MS 24 Distribution Ordering System Setup and Establishment in accordance with the terms of the agreement. FOB: Destination PSC CD: AN14				
				NET AMT	(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
002401					(b) (4)
	Funding FFP PURCHASE REQUEST NUMBER: 0011560606				
				NET AMT	(b) (4)
	ACRN AA CIN: GFEBS001156060600024				(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0025			Job		(b) (4)
	MS 25 Distribution AZD 7422 COST MS 25 Distribution AZD 7422 in accordance with the terms of the agreement. FOB: Destination PSC CD: AN14				
				ESTIMATED COST	(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
002501					(b) (4)
	Funding COST PURCHASE REQUEST NUMBER: 0011560606				
				ESTIMATED COST	(b) (4)
	ACRN AA CIN: GFEBS001156060600025				(b) (4)

INSPECTION AND ACCEPTANCE TERMS

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
000201	N/A	N/A	N/A	N/A
0003	Destination	Government	Destination	Government
000301	N/A	N/A	N/A	N/A
0004	Destination	Government	Destination	Government
000401	N/A	N/A	N/A	N/A
0005	Destination	Government	Destination	Government
000501	N/A	N/A	N/A	N/A
0006	Destination	Government	Destination	Government
000601	N/A	N/A	N/A	N/A
0007	Destination	Government	Destination	Government
000701	N/A	N/A	N/A	N/A
0008	Destination	Government	Destination	Government
000801	N/A	N/A	N/A	N/A
0009	Destination	Government	Destination	Government
000901	N/A	N/A	N/A	N/A
0010	Destination	Government	Destination	Government
001001	N/A	N/A	N/A	N/A
0011	Destination	Government	Destination	Government
001101	N/A	N/A	N/A	N/A
0012	Destination	Government	Destination	Government
001201	N/A	N/A	N/A	N/A
0013	Destination	Government	Destination	Government
001301	N/A	N/A	N/A	N/A
0014	Destination	Government	Destination	Government
001401	N/A	N/A	N/A	N/A
0015	Destination	Government	Destination	Government
001501	N/A	N/A	N/A	N/A
0016	Destination	Government	Destination	Government
001601	N/A	N/A	N/A	N/A
0017	Destination	Government	Destination	Government
001701	N/A	N/A	N/A	N/A
0018	Destination	Government	Destination	Government
001801	N/A	N/A	N/A	N/A
0019	Destination	Government	Destination	Government
001901	N/A	N/A	N/A	N/A
0020	Destination	Government	Destination	Government
002001	N/A	N/A	N/A	N/A
0021	Destination	Government	Destination	Government
002101	N/A	N/A	N/A	N/A
0022	Destination	Government	Destination	Government
002201	N/A	N/A	N/A	N/A

0023	Destination	Government	Destination	Government
002301	N/A	N/A	N/A	N/A
0024	Destination	Government	Destination	Government
002401	N/A	N/A	N/A	N/A
0025	Destination	Government	Destination	Government
002501	N/A	N/A	N/A	N/A

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE (b) (4)	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
0001		1	N/A FOB: Destination	
000101		N/A	N/A	N/A
0002		1	N/A FOB: Destination	
000201		N/A	N/A	N/A
0003		1	N/A FOB: Destination	
000301		N/A	N/A	N/A
0004		1	N/A FOB: Destination	
000401		N/A	N/A	N/A
0005		1	N/A FOB: Destination	
000501		N/A	N/A	N/A
0006		1	N/A FOB: Destination	
000601		N/A	N/A	N/A
0007		1	N/A FOB: Destination	
000701		N/A	N/A	N/A
0008		1	N/A FOB: Destination	
000801		N/A	N/A	N/A
0009		1	N/A FOB: Destination	
000901		N/A	N/A	N/A

0010	(b) (4)	1	N/A FOB: Destination	
00100		N/A	N/A	N/A
0011		1	N/A FOB: Destination	
00110		N/A	N/A	N/A
0012		(b) (4)	N/A FOB: Destination	
00120		N/A	N/A	N/A
0013		1	N/A FOB: Destination	
00130		N/A	N/A	N/A
0014		1	N/A FOB: Destination	
00140		N/A	N/A	N/A
0015		1	N/A FOB: Destination	
00150		N/A	N/A	N/A
0016		1	N/A FOB: Destination	
00160		N/A	N/A	N/A
0017		1	N/A FOB: Destination	
00170		N/A	N/A	N/A
0018		1	N/A FOB: Destination	
00180		N/A	N/A	N/A
0019		1	N/A FOB: Destination	
00190		N/A	N/A	N/A
0020		1	N/A FOB: Destination	
00200		N/A	N/A	N/A

0021	(b) (4)	1	N/A FOB: Destination	
002101		N/A	N/A	N/A
0022		1	N/A FOB: Destination	
002201		N/A	N/A	N/A
0023		1	N/A FOB: Destination	
002301		N/A	N/A	N/A
0024		1	N/A FOB: Destination	
002401		N/A	N/A	N/A
0025			N/A FOB: Destination	
002501		N/A	N/A	N/A

Section G - Contract Administration Data

ACCOUNTING AND APPROPRIATION DATA

AA: 021202020212040000066464325 5 S.0074658.5.23 6100.9000021001
COST CODE: A5XAH
AMOUNT: (b) (4)

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	000101	GFEBS001156060600001	(b) (4)
	000201	GFEBS001156060600002	(b) (4)
	000301	GFEBS001156060600003	(b) (4)
	000401	GFEBS001156060600004	(b) (4)
	000501	GFEBS001156060600005	(b) (4)
	000601	GFEBS001156060600006	(b) (4)
	000701	GFEBS001156060600007	(b) (4)
	000801	GFEBS001156060600008	(b) (4)
	000901	GFEBS001156060600009	(b) (4)
	001001	GFEBS001156060600010	(b) (4)
	001101	GFEBS001156060600011	(b) (4)
	001201	GFEBS001156060600012	(b) (4)
	001301	GFEBS001156060600013	(b) (4)
	001401	GFEBS001156060600014	(b) (4)
	001501	GFEBS001156060600015	(b) (4)
	001601	GFEBS001156060600016	(b) (4)
	001701	GFEBS001156060600017	(b) (4)
	001801	GFEBS001156060600018	(b) (4)
	001901	GFEBS001156060600019	(b) (4)
	002001	GFEBS001156060600020	(b) (4)
	002101	GFEBS001156060600021	(b) (4)
	002201	GFEBS001156060600022	(b) (4)
	002301	GFEBS001156060600023	(b) (4)
	002401	GFEBS001156060600024	(b) (4)
	002501	GFEBS001156060600025	(b) (4)

AGREEMENT ADMINISTRATION
A. In no event shall any understanding of agreement, modification, change order, or other matter in deviation from the terms and conditions of this agreement between the contractor and a person other than the Agreement Officer be effective or binding upon the Government. All such actions must be formalized by a proper agreement document executed by the Agreement Officer.
B. The telephone number and e-mail addresss of the Agreement Officer and Agreement Specialist are:
Agreements Officer:
(b) (6)
Telephone: (b) (6)
E-mail: (b) (6)
Agreement Specialist:
(b) (6)
Telephone: (b) (6)
E-mail: (b) (6)
C. The telephone number and e-mail address of the Government Program Manager is:
Government Program Manager:
(b) (6)
Telephone: (b) (6)

E-mail: (b) (6), (b) (4)

ACCOUNTING AND APPROPRIATION DATA

AA: 021202020212040000664643255 S.0074658.5.23 6100.9000021001
COST CODE: A5XAH
AMOUNT: (b) (4)

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	000101	GFEBS001156060600001	(b) (4)
	000201	GFEBS001156060600002	(b) (4)
	000301	GFEBS001156060600003	(b) (4)
	000401	GFEBS001156060600004	(b) (4)
	000501	GFEBS001156060600005	(b) (4)
	000601	GFEBS001156060600006	(b) (4)
	000701	GFEBS001156060600007	(b) (4)
	000801	GFEBS001156060600008	(b) (4)
	000901	GFEBS001156060600009	(b) (4)
	001001	GFEBS001156060600010	(b) (4)
	001101	GFEBS001156060600011	(b) (4)
	001201	GFEBS001156060600012	(b) (4)
	001301	GFEBS001156060600013	(b) (4)
	001401	GFEBS001156060600014	(b) (4)
	001501	GFEBS001156060600015	(b) (4)
	001601	GFEBS001156060600016	(b) (4)
	001701	GFEBS001156060600017	(b) (4)
	001801	GFEBS001156060600018	(b) (4)
	001901	GFEBS001156060600019	(b) (4)
	002001	GFEBS001156060600020	(b) (4)
	002101	GFEBS001156060600021	(b) (4)
	002201	GFEBS001156060600022	(b) (4)
	002301	GFEBS001156060600023	(b) (4)
	002401	GFEBS001156060600024	(b) (4)
	002501	GFEBS001156060600025	(b) (4)

CLAUSES INCORPORATED BY FULL TEXT

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

(a) Definitions. As used in this clause—

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

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

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

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

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

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

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

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

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

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

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

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

(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.

_____

(Contracting Officer: Insert applicable invoice and receiving report document type(s) for fixed price line items that require shipment of a deliverable.)

(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.

_____

(Contracting Officer: Insert either "Invoice 2in1" or the applicable invoice and receiving report document type(s) for fixed price line items for services.)

(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*

Field Name in WAWF	*Data to be entered in WAWF*
Pay Official DoDAAC	HQ0490
Issue By DoDAAC	W911QY
Admin DoDAAC**	W911QY
Inspect By DoDAAC	W56XNH
Ship To Code	W56XNH

(*Contracting Officer: Insert applicable DoDAAC information. If multiple ship to/acceptance locations apply, insert "See Schedule" or "Not applicable.")

(**Contracting Officer: If the contract provides for progress payments or performance-based payments, insert the DoDAAC for the contract administration office assigned the functions under FAR 42.302(a)(13).)

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

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

(g) WAWF point of contact.

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

(b) (6) [redacted]

(b) (6) [redacted]

[redacted]

[redacted]

[redacted]

(b) (6) [redacted]

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

(End of clause)

Section I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

52.232-22	Limitation Of Funds	APR 1984

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 CONTRACT ID CODE	PAGE OF PAGES
	1 | 2

2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00001	12-Nov-2020	0011560606	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK DIVISION 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		9A. AMENDMENT OF SOLICITATION NO.
ASTRAZENECA PHARMACEUTICALS LP 1800 CONCORD PIKE WILM NGTON DE 19803-2902		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2190001
CODE 36WK2 FACILITY CODE	X	10B. DATED (SEE ITEM 13) 09-Oct-2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

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

12. ACCOUNTING AND APPROPRIATION DATA (If required)

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

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

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

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

X D. OTHER (Specify type of modification and authority)
In accordance with Article 5 of the agreement.

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

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6)
The purpose of this modification is to designate this agreement as an HRPAS rated order (b) (4), by incorporating a DPAS rating in SF 26 block 1 of the agreement and adding clause A.19.M to the agreement. All other terms and conditions remain the same and in full force and effect.

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) TEL: (b) (6) EMAIL: (b) (6)
15B. CONTRACT (b) (6) (Signature of p)	15C. DATE SIGNED Nov 13, 2020
16B. (b) (6) A BY er)	16C. DATE SIGNED 13 Nov 2020

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:

P00001

A. The purpose of this modification is to designate this agreement as an Health Resources Priority Allocation (HRPAS) rated order (45 CFR 101) as approved by the Secretary of Health and Human Services on 10 November 2020

B. Block 1 of the agreement SF 26 is hereby revised to incorporate a DPAS rating of (b) (4) .

C. The Awardee is hereby authorized to effect this rating on all vendors necessary to support the prototype development. Companies are required by law to accept rated orders and to provide preferential scheduling even over previously accepted orders if necessary to meet required delivery date(s)

D. Article 19, paragraph M is hereby incorporated to add the following:

   a. "This is a rated order certified for national defense, emergency preparedness, and energy program use, and the Awardee shall follow all the requirements of the Defense Priorities and Allocations System regulation (15 CFR 700)."

E. All other terms and conditions remain the same and in full force and effect.

SECTION A - SOLICITATION/CONTRACT FORM

The DPAS code (b)(4) has been added.

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 | 3

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00002	03-Dec-2020	0011560606	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK DIVISION 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
ASTRAZENECA PHARMACEUTICALS LP 1800 CONCORD PIKE WILMINGTON DE 19803-2902		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2190001
	X	10B. DATED (SEE ITEM 13) 09-Oct-2020
CODE 36WK2	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

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

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

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

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

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

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

X D. OTHER (Specify type of modification and authority)
In accordance with Article 5 of the agreement.

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

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6)
The purpose of this modification is to increase the value and funding of CLN 0004 by (b) (4), and decrease the value and funding of CLN 0008 by (b) (4).

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

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
	(b) (6) / CONTRACTING OFFICER TEL: (b) (6) EMAIL: (b) (6)

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(Signature of person authorized to sign)		BY (b) (6) (Signature of Contracting Officer)	03-Dec-2020

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:

P00002

A. The purpose of this modification is as follows:

1. CLIN 0004 is hereby increased by (b) (4) from (b) (4) to (b) (4).
2. CLIN 00401, ACRN AA, is hereby increased by (b) (4) from (b) (4) to (b) (4).
3. CLIN 0008 is hereby decreased by (b) (4) from (b) (4) to (b) (4).
4. CLIN 000801 is hereby decreased by (b) (4) from (b) (4) to (b) (4).

B. As a result of the the changes indicated in paragraph A, the total value of this agreement remains unchanged.

C. The parties hereby agree that changes effected by this modification constitute both the consideration and the equitable adjustment due under any clause of this agreement resulting from the incorporation of the changes identified in paragraph A.

D. All other terms and conditions remain the same and in full force and effect.

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0004

The unit price amount has increased by (b) (4) from (b) (4) to (b) (4).
The total cost of this line item has increased by (b) (4) from (b) (4) to (b) (4).

CLIN 0008

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4).
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4).

SECTION F - DELIVERIES OR PERFORMANCE

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

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
30-OCT-2020	1	N/A FOB: Destination	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
30-OCT-2020		N/A FOB: Destination	

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

SUBCLIN 000401:

AA: 021202020212040000066464325 5 S.0074658.5.23 6100.9000021001 A5XAH (CIN GFEBS001156060600004) was increased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 000801:

AA: 021202020212040000066464325 5 S.0074658.5.23 6100.9000021001 A5XAH (CIN GFEBS001156060600008) was decreased by (b) (4) from (b) (4) to (b) (4)

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 | 6

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00003	15-Jan-2021	0011560606	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK DIVISION 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
ASTRAZENECA PHARMACEUTICALS LP 1800 CONCORD PIKE WILMINGTON DE 19803-2902		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2190001
	X	10B. DATED (SEE ITEM 13) 09-Oct-2020
CODE 36WK2	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

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

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

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

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

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

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

X D. OTHER (Specify type of modification and authority)
In accordance with Article 5 of the Agreement.

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

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6)
The purpose of this modification is to definitize costs by revising CLN and funding values, and incorporate Government Furnished Equipment under Appendix D of the Agreement. All other terms and conditions remain the same and in full force and effect.

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

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
	(b) (6) / CONTRACTING OFFICER TEL: (b) (6) EMAIL: (b) (6)

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(Signature of person authorized to sign)		BY (b) (6) (Signature of Contracting Officer)	15-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:

P00003

A. The purpose of this modification is as follows.

1. Costs are hereby definitized based on the Governments cost share submitted under spreadsheet "Cost_Proposal_Spreadsheet_AZD7422_response 07Dec20 v2" dated 4 December 2020.

2. As a result, the total cost of this agreement is hereby reduced by (b) (4), from (b) (4), to (b) (4).

3. The following CLINS are hereby revised to account for the change:

CLIN	BY	FROM	TO
0004	(b) (4)		
0005	(b) (4)		
0006	(b) (4)		
0008	(b) (4)		
0009	(b) (4)		
0010	(b) (4)		
0011	(b) (4)		
0012	(b) (4)		
0020	(b) (4)		
0021	(b) (4)		
0022	(b) (4)		
0023	(b) (4)		

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

5. Funding under the following CLINS is hereby revised to account for the definitization:

CLIN	BY	FROM	TO
0004	(b) (4)		
0005	(b) (4)		
0006	(b) (4)		
0008	(b) (4)		
0009	(b) (4)		
0010	(b) (4)		
0011	(b) (4)		
0012	(b) (4)		
0020	(b) (4)		
0021	(b) (4)		
0022	(b) (4)		
0023	(b) (4)		

6. Government Furnished Equipment is hereby added to Appendix D of the agreement, under Attachment 1 to this modification.

7. The terms of the cost share for StormChaser costs are hereby revised to (b) (4) with no changes to the Awardee's contribution. (b) (4)

B. The parties hereby agree that changes effected by this modification constitute both the consideration and the equitable adjustment due under any clause of this agreement resulting from the incorporation of the changes identified in paragraph A.

C. All other terms and conditions remain the same and in full force and effect.

SECTION A - SOLICITATION/CONTRACT FORM

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

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0004
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4).
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4).

CLIN 0005
The unit price amount has increased by (b) (4) from (b) (4) to (b) (4).
The total cost of this line item has increased by (b) (4) from (b) (4) to (b) (4).

CLIN 0006
The unit price amount has increased by (b) (4) from (b) (4) to (b) (4).
The total cost of this line item has increased by (b) (4) from (b) (4) to (b) (4).

CLIN 0008
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4).
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4).

CLIN 0009
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4).
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4).

CLIN 0010
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4).
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4).

CLIN 0011
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4).
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4).

CLIN 0012
The estimated/max cost has increased by (b) (4) from (b) (4) to (b) (4).
The total cost of this line item has increased by (b) (4) from (b) (4) to (b) (4).

CLIN 0020
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4).
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4).

CLIN 0021
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4).
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4).

CLIN 0022
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4).
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4).

CLIN 0023
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4).
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4).

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule item for CLIN 0005 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
30-NOV-2020	1	N/A FOB: Destination	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
30-NOV-2020		N/A FOB: Destination	

The following Delivery Schedule item for CLIN 0010 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
(b) (4)	1	N/A FOB: Destination	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
(b) (4)	1	N/A FOB: Destination	

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

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

SUBCLIN 000401:

AA: 021202020212040000066464325 5 S.0074658.5.23 6100.9000021001 A5XAH (CIN GFEBS001156060600004) was decreased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 000501:

AA: 021202020212040000066464325 5 S.0074658.5.23 6100.9000021001 A5XAH (CIN GFEBS001156060600005) was increased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 000601:

AA: 021202020212040000066464325 5 S.0074658.5.23 6100.9000021001 A5XAH (CIN GFEBS001156060600006) was increased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 000801:

AA: 021202020212040000066464325 5 S.0074658.5.23 6100.9000021001 A5XAH (CIN

GFEBS001156060600008) was decreased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 000901:

AA: 0212020202120400000664643255 S.0074658.5.23 6100.9000021001 A5XAH (CIN GFEBS001156060600009) was decreased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 001001:

AA: 0212020202120400000664643255 S.0074658.5.23 6100.9000021001 A5XAH (CIN GFEBS001156060600010) was decreased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 001101:

AA: 0212020202120400000664643255 S.0074658.5.23 6100.9000021001 A5XAH (CIN GFEBS001156060600011) was decreased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 001201:

AA: 0212020202120400000664643255 S.0074658.5.23 6100.9000021001 A5XAH (CIN GFEBS001156060600012) was increased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 002001:

AA: 0212020202120400000664643255 S.0074658.5.23 6100.9000021001 A5XAH (CIN GFEBS001156060600020) was decreased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 002101:

AA: 0212020202120400000664643255 S.0074658.5.23 6100.9000021001 A5XAH (CIN GFEBS001156060600021) was decreased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 002201:

AA: 0212020202120400000664643255 S.0074658.5.23 6100.9000021001 A5XAH (CIN GFEBS001156060600022) was decreased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 002301:

AA: 0212020202120400000664643255 S.0074658.5.23 6100.9000021001 A5XAH (CIN GFEBS001156060600023) was decreased by (b) (4) from (b) (4) to (b) (4)

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 | 4

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00005	15-Mar-2021	0011560606	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK DIVISION 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
ASTRAZENECA PHARMACEUTICALS LP 1800 CONCORD PIKE WILMINGTON DE 19803-2902		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2190001
	X	10B. DATED (SEE ITEM 13) 09-Oct-2020
CODE 36WK2	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

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

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

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

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

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

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

X D. OTHER (Specify type of modification and authority)
In accordance with Artricle 5 of the agreement.

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

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6) [redacted]
The purpose of this modification is to revise costs and funding under CLINs 0009 - 0011, and revise Article 4 and 6 of the Agreement. Alll other terms and conditions remain the same and in full force and effect.

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) [redacted] / CONTRACT SPECIALIST TEL: (b) (6) [redacted] EMAIL: (b) (6) [redacted]

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(Signature of person authorized to sign)		BY (b) (6) [redacted] (Signature of Contracting Officer)	15-Mar-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:

P00004

A. The purpose of this modification is as follows.

1. In accordance with Appendix B of the Agreement, the costs for CLINs 0009 – 0011 are hereby reduced to incorporate a (b) (4) to the Stormchaser Trial based on the Government's cost share identified in modification P00003 as follows:

Stormchaser

CLIN	BY	FROM	TO
0009	(b) (4)		
0010	(b) (4)		
0011	(b) (4)		
Total	(b) (4)		

2. As a result, the total cost of this agreement is hereby reduced by (b) (4), from (b) (4), to (b) (4).

3. Funding under the following CLINS is hereby reduced based on paragraph A.1 as follows:

Stormchaser

CLIN	BY	FROM	TO
000901	(b) (4)		
001001	(b) (4)		
001101	(b) (4)		
Total	(b) (4)		

4. As a result, the total funding of this agreement is hereby reduced by (b) (4), from (b) (4), to (b) (4).

5. Article 4 of the agreement is hereby revised to replace the Agreements Officer and Agreements Specialist with the following:

Government Representatives:
Agreements Officer (AO)
(b) (6), (b) (4)
ACC-APG-Fort Detrick
110 Thomas Johnson Dr.
Frederick, MD 21702
(b) (6), (b) (4)

Other Transaction Agreement Specialist (OTAS)
(b) (6), (b) (4)
ACC-APG-Fort Detrick
110 Thomas Johnson Dr.
Frederick, MD 21702
(b) (6), (b) (4)

6. Article 6, paragraph B, is hereby revised to add the following:
"Title and Physical Risk of Loss. Title to the product will transfer to the Government when the product leaves the Awardee's facility for shipment to the distributor(s). Risk of Loss will be retained by the Awardee until the product is delivered to the administering hospitals and other designated healthcare providers ("Providers") by Distributor, at which time title and risk of loss and damages then passes from Government and Awardee respectively, immediately to the Provider."

B. The parties hereby agree that changes effected by this modification constitute both the consideration and the equitable adjustment due under any clause of this agreement resulting from the incorporation of the changes identified in paragraph A.

C. All other terms and conditions remain the same and in full force and effect.

SECTION A - SOLICITATION/CONTRACT FORM

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

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0009
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4).
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4).

CLIN 0010

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4).
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4).

CLIN 0011

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4).
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4).

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

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

SUBCLIN 000901:

AA: 021202020212040000066464325 5 S.0074658.5.23 6100.9000021001 A5XAH (CIN GFEBS001156060600009) was decreased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 001001:

AA: 021202020212040000066464325 5 S.0074658.5.23 6100.9000021001 A5XAH (CIN GFEBS001156060600010) was decreased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 001101:

AA: 021202020212040000066464325 5 S.0074658.5.23 6100.9000021001 A5XAH (CIN GFEBS001156060600011) was decreased by (b) (4) from (b) (4) to (b) (4)

(End of Summary of Changes)