AWARD/CONTRACT

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING	PAGE 1 OF PAGES 84
2. CONTRACT *(Proc. Inst. Ident.)* NO. W15QKN2191003	3. EFFECTIVE DATE 28 Oct 2020	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 0011567172	

5. ISSUED BY CODE W15QKN US ARMY CONTRACTING COMMAND PHIPPS ROAD PICAT NNY NJ 07806-5000		6. ADMINISTERED BY *(If other than Item 5)* CODE **See Item 5**	
7. NAME AND ADDRESS OF CONTRACTOR *(No., street, city, county, state and zip code)* ASTRAZENECA PHARMACEUTICALS LP 1800 CONCORD P KE WILM NGTON DE 19803-2902		8. DELIVERY [ ] FOB ORIGIN [X] OTHER *(See below)* 9 DISCOUNT FOR PROMPT PAYMENT	
		10 SUBMIT INVOICES *(4 copies unless otherwise specified)* TO THE ADDRESS SHOWN IN:	ITEM
CODE 36WK2	FACILITY CODE		
11. SHIP TO/MARK FOR CODE **See Schedule**		12. PAYMENT WILL BE MADE BY CODE HQ0337 DFAS COLUMBUS CENTER DFAS COLUMBUS/NORTH ENTITLEMENT P.O BOX 182317 COLUMBUS OH 43218-2266	
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: [ ] 10 U.S.C. 2304(c)( ) [ ] 41 U.S.C. 253(c)( )		14. ACCOUNTING AND APPROPRIATION DATA **See Schedule**	

15A. ITEM NO.	15B. SUPPLIES/ SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	SEE SCHEDULE				
				15G. TOTAL AMOUNT OF CONTRACT	**$1,208,933,813.79**

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

17 [X] CONTRACTOR'S NEGOTIATED AGREEMENT Contractor is required to sign this document and return1 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 BY _____ *(Signature of person authorized to sign)*	19C. DATE SIGNED
20B. UNITED STATES OF AMERICA (b) (6) BY _____ *(Signature of Contracting Officer)*	20C. DATE SIGNED 28-Oct-2020

Section A - Solicitation/Contract Form

EXECUTIVE SUMMARY

1) This Undefinitized Project Agreement (UPA) is being issued by The Army Contracting Command – New Jersey to AstraZeneca Pharmaceuticals LP (AstraZeneca), 1800 Concord Pike, Wilmington, DE, 19803-2902.

2) Both parties agree that the general scope of this UPA requires AstraZeneca to Conduct Phase 3 clinical trials and demonstrate the ability to manufacture and distribute 100 Million (M) doses of the ChAdOx1 nCoV-19 vaccine (now referred to as AZD1222) to the United States Government to prevent the general population from developing symptoms of the COVID-19 infection.

3) This action has a total Firm Fixed Price value of $1,208,933,813.79. It is not anticipated that the total value of this action will increase during the definitization process.

4) Funding is obligated in the total amount of $1,208,933,813.79, however performance is only authorized up to (b) (4) of total UPA value prior to definitization.

5) The anticipated Period of Performance is 39 months from the effective date, ending 31-December 2023.

6) The Effective Date of this UPA is identified in Block 3 on Page 1 of this agreement.

7) The estimated preliminary delivery schedule, setting forth the quantities and timing of delivery of each shipment of AZD1222 initially projected by AstraZeneca as of the Effective Date of this UPA, is set out in Section H Table 2: Payable Milestones. AstraZeneca shall provide a Dose Tracking Tool that will include updated estimates, based on AstraZeneca's knowledge, of anticipated quantities and timing. As soon as reasonably possible, and in any event not later than (b) (4) prior to each anticipated delivery, AstraZeneca shall use commercially reasonable efforts to provide a firm and final delivery schedule for each shipment setting forth the quantities of AZD1222 and the date for delivery of each shipment.

8) The Representations and Certifications made by AstraZeneca in the System for Award Management (SAM) are hereby incorporated into this contract by reference.

9) The terms and conditions set forth in this UPA are not expected to materially change prior to definitization, however aspects may be negotiated prior to definitization.

10) This contract shall have a Health Resources Priotities and Allocation System (HRPAS) priority rating of DO-HR. See Section H for additional information.

Section B - Supplies or Services and Prices

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

Milestone 1
FFP
To be invoiced upon agreement award.
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AA
CIN: GFEBS001156717200001

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

Milestone 2
FFP
DS (b) (4) Expected completion date of (b) (4)

FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AA
CIN: GFEBS001156717200002

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

Milestone 3
FFP
DP(b) (4) Expected completion date of(b) (4)

FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AA
CIN: GFEBS001156717200003

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

Milestone 4
FFP
(b) (4) of commercial scale DS (GMP or non-GMP). Expected completion date of(b) (4)

FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AA
CIN: GFEBS001156717200004

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0005		1	Lot	(b) (4)	[redacted]

Milestone 5
FFP
1151RM Prelim DART study report. Expected completion date of (b) (4)

FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AA
CIN: GFEBS001156717200005

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0006		1	Lot	(b) (4)	[redacted]

Milestone 6
FFP
(b) (4)

FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AA
CIN: GFEBS001156717200006

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0007		1	Lot	(b) (4)	[redacted]

Milestone 7
FFP
(b) (4) [redacted]

FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4) [redacted]

ACRN AB
CIN: GFEBS001156717200007

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0008		1	Lot	(b) (4)	[redacted]

Milestone 8
FFP
(b) (4) [redacted]

FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4) [redacted]

ACRN AB
CIN: GFEBS001156717200008

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

Milestone 9
FFP
(b) (4)

FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200009

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

Milestone 10
FFP
(b) (4) of commercial scale DS (GMP or non-GMP). Expected completion date of (b) (4)

FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200010

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

Milestone 11
FFP
DP Validation Report. Expected completion date of (b) (4)

FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200011

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0012		1	Lot	(b) (4)	

Milestone 12
FFP
DS Validation Report. Expected completion date of (b) (4) .
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200012

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0013		1	Lot	(b) (4)	[redacted]

Milestone 13
FFP
(b) (4) [redacted]
Expected completion date of (b) (4) [redacted]

FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4) [redacted]

ACRN AB
CIN: GFEBS001156717200013

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0014		1	Lot	(b) (4)	[redacted]

Milestone 14
FFP
(b) (4) [redacted] of commercial scale DS (GMP or non-GMP). Expected completion date of (b) (4) [redacted]

FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4) [redacted]

ACRN AB
CIN: GFEBS001156717200014

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

Milestone 15
FFP
Deliver (b) (4) Doses FP to (b) See Article I.C.10 for Due Date.
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200015

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

Milestone 16
FFP
Deliver (b) (4) Doses FP to (b) See Article I.C.10 for Due Date.

FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200016

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0017		1	Lot	(b) (4)	[redacted]

Milestone 17a
FFP
Deliver (b) (4) Doses FP (b) (4) See Article I.C.10
for Due Date.
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200017

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0018		1	Lot	(b) (4)	[redacted]

Milestone 17b
FFP
Pharmacovigilance. Concurrent with Milestone 17a.
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200018

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

Milestone 18a
FFP
Deliver (b) (4) Doses FP (b) (4) See Article I.C.10
for Due Date.
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200019

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

Milestone 18b
FFP
Pharmacovigilance. Concurrent with Milestone 18a.
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200020

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

Milestone 19
FFP
Pediatric Phase 3 Study. Details to be finalized prior to work beginning on Pediatric Phase 3 Study. This Milestone represents a rough order of magnitude, and additional Milestones will be added upon a future bilateral modification.
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200021

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

Milestone 20
FFP
BLA Submission. Expected completion date of (b) (4)
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200022

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

Milestone 21
FFP
Phase 3 LSLV. Expected completion date of (b) (4)
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200023

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0024		1	Lot	(b) (4)	

Milestone 22
FFP
Ph3 Final CSR. Expected completion date of (b) (4)
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200024

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0025		1	Lot	(b) (4)	[redacted]

Milestone 23
FFP
(b) (4) enrollment of (b) (4) (DOD Approval of (b) patient increment).
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4) [redacted]

ACRN AB
CIN: GFEBS001156717200025

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0026		1	Lot	(b) (4)	[redacted]

Milestone 24
(b) (4) enrollment of (b) (DOD Approval of (b) patient increment).
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4) [redacted]

ACRN AB
CIN: GFEBS001156717200026

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0027		1	Lot	(b) (4)	[redacted]

Milestone 25
FFP
(b) (4) enrollment of (b) (DOD Approval of (b) patient increment).
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200027

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0028		1	Lot	(b) (4)	[redacted]

Milestone 26
FFP
(b) (4) enrollment of (b) (DOD Approval of (b) patient increment).
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200028

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0029		1	Lot	$(b) (4)	

Milestone 27
FFP
(b) (4) enrollment of (b) (DOD Approval of (b) patient increment).
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200029

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0030		1	Lot	(b) (4)	

Milestone 28
FFP
(b) (4) enrollment of (b) (DOD Approval of (b) patient increment).
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200030

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0031		1	Lot	$(b) (4)	

Milestone 29
FFP
(b) (4) enrollment of (b) (DOD Approval of (b) patient increment).
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200031

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0032		1	Lot	(b) (4)	

Milestone 30
FFP
(b) (4) enrollment of (b) (DOD Approval of (b) patient increment).
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200032

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0033		1	Lot	(b) (4)	[redacted]

Milestone 31
FFP
(b) (4) enrollment of (b) (DOD Approval of (b) patient increment).
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4) [redacted]

ACRN AB
CIN: GFEBS001156717200033

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0034		1	Lot	(b) (4)	[redacted]

Milestone 32
FFP
(b) (4) enrollment of (b) (DOD Approval of (b) patient increment)
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4) [redacted]

ACRN AB
CIN: GFEBS001156717200034

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0035		1	Lot	(b) (4)	[redacted]

Milestone 33
FFP
(b) (4) enrollment of (b) (DOD Approval of (b) patient increment).
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200035

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0036		1	Lot	(b) (4)	[redacted]

Milestone 34
FFP
(b) (4) enrollment of (b) (DOD Approval of (b) patient increment).
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200036

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0037		1	Lot	(b) (4)	[redacted]

Milestone 35
FFP
(b) (4) enrollment of (b) (DOD Approval of (b) patient increment).
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200037

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0038		1	Lot	(b) (4)	[redacted]

Milestone 36
FFP
(b) (4) enrollment of (b) (DOD Approval of (b) patient increment).
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200038

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0039		1	Lot	(b) (4)	[redacted]

Milestone 37
FFP
(b) (4) enrollment of (b) (DOD Approval of (b) patient increment).
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200039

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0040		1	Lot	(b) (4)	[redacted]

Milestone 38
FFP
(b) (4) enrollment of (b) (DOD Approval of (b) patient increment).
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200040

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0041		1	Lot	(b) (4)	[redacted]

Milestone 39
FFP
(b) (4) enrollment of (b) (DOD Approval of (b) patient increment).
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200041

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0042		1	Lot	(b) (4)	[redacted]

Milestone 40
FFP
(b) (4) enrollment of (b) (DOD Approval of (b) patient increment).
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200042

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0043		1	Lot	(b) (4)	[redacted]

Milestone 41
FFP
(b) (4) enrollment of (b) (DOD Approval of (b) patient increment).
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200043

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0044		1	Lot	(b) (4)	[redacted]

Milestone 42
FFP
(b) (4) enrollment of (b) (DOD Approval of (b) patient increment).
FOB: Destination
PURCHASE REQUEST NUMBER: 0011567172
PSC CD: AN13

NET AMT (b) (4)

ACRN AB
CIN: GFEBS001156717200044

Section C - Descriptions and Specifications

STATEMENT OF WORK

STATEMENT OF WORK

1. **Prototype Delivery Contract (100M Doses; (b) (4))**
   1.1. Manufacturing Demonstration (DOD WBS1; BARDA WBS1&2)
      1.1.1. Technology transfer, process development and process characterization to enable large scale manufacturing and distribution
         1.1.1.1. Drug Substance
            1.1.1.1.1. Process TT
            1.1.1.1.2. Analytical Method Transfer and Validation
            1.1.1.1.3. Stability
            1.1.1.1.4. DS Shipping Studies
            1.1.1.1.5. Comparability
         1.1.1.2. Drug Product
            1.1.1.2.1. Process TT
            1.1.1.2.2. Analytical Method Transfer and Validation
            1.1.1.2.3. Stability
            1.1.1.2.4. DP Shipping Studies
            1.1.1.2.5. Comparability
   1.2. Demonstration DS Manufacture (DOD WBS2; BARDA WBS 2)
      1.2.1. Manufacture & Release
      1.2.2. Storage/Shipping
   1.3. Demonstration DP Manufacture (DOD WBS3; BARDA WBS 3)
      1.3.1. Manufacture & Release
      1.3.2. Shipping
   1.4. Demonstration DP Pack/Label (DOD WBS4)
      1.4.1. Pack/Label
      1.4.2. Storage/Shipping
   1.5. Nonclinical Toxicology Demonstration (DOD WBS5)
      1.5.1. Dose-ranging developmental toxicology ((b) (4)
      1.5.2. GLP Prenatal / Postnatal Developmental Toxicity Study ((b) (4))
   1.6. Phase 3 Clinical Study (Adult) (DOD WBS6)
   1.7. Phase 2/3 Clinical Study (Pediatric) (DOD WBS7)
   1.8. HA Authorization/Approval (DOD WBS8)
      1.8.1. EUA
      1.8.2. BLA
      1.8.3. PV
   1.9. Project Management (DOD WBS9)

1. Prototype Delivery Contract (100M Doses; (b) (4))

1.1. Manufacturing Demonstration (DOD Contract 1 WBS1)

1.1.1. Technology transfer, process development and process characterization to enable large scale manufacturing and distribution

1.1.1.1. Drug Substance (DS)

1.1.1.1.1. Process TT

The DS process will be developed from the (b) (4) and associated downstream process, used to support Ph3 in US, and scaled to (b) (4) Activities will focus primarily on

- Establishment of (b) (4) to support the Drug Substance manufacture

- Evaluation and optimization of the upstream and downstream processes to ensure robust manufacturing operations and fit to plant
- Evaluation of process changes that may enhance process performance or enable more streamlined manufacturing operations
- Process characterization

The process will be (b) (4) with the process development activities. (b) (4) A pre-validation and validation strategy, based on an assessment of control and consistency through critical review, and experience gained through the tech transfer process will be developed and discussed with the FDA.

AstraZeneca shall (b) (4) to perform tech transfers.

If there are problems with the facility, equipment or capacity (b) (4) the USG will actively engage to ensure timely and effective resolution of those issues (b) (4) (b) (4)

All information related to raw materials, manufacture, testing and release activities (b) (4) (b) (4)

Other supporting work will be conducted as necessary/appropriate in support of licensure to possibly include the following.

(b) (4)

1.1.1.1.2. DS Analytical Method Transfer and Validation

AstraZeneca (b) (4) to develop Analytical Method Transfer Protocols and Reports. All information will be delivered by (b) (4) AstraZeneca.

Proposed assays for test and release of DS, DS comparability, and DS stability are specified in Table 1.1.1.1.2-A, Table 1.1.1.1.2-B and Table 1.1.1.1.2-C, respectively. After sufficient experience and completion of validation testing may be reduced or altered based on experience gained during the tech transfer, validation and manufacturing processes. AstraZeneca and the Government recognize that different analytical methods may need to be developed and validated to support regulatory approval.

Table 1.1.1.1.2-A: Drug Substance Release Tests Planned, As Necessary

Method Description	DS In-Process	DS Release
(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]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]		[redacted]
[redacted]		[redacted]

[redacted]

Method	Critical Quality Attribute Evaluated	Test Purpose
(b) (4) [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Table 1.1.1.1.2-C: Drug Substance Stability Assays Planned, As Necessary

Method Description	DS Stability
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

1.1.1.1.3. DS Stability

AstraZeneca (b) (4) [redacted] to develop a DS Stability Study Plan (Table 1.1.1.1.3) and to conduct DS stability testing. (b) (4) [redacted]

(b) (4)

Table 1.1.1.1.3: Drug Substance Stability Test Schedule

Test	Method	Temperature	Time-points in Months																
			T0*	0.25	0.5	0.75	1	1.5	2	3	4	5	6	7	8	9	10	11	12	18	24
(b) (4)																					

1.1.1.1.4. DS Shipping Studies

AstraZeneca shall contract with established service providers to conduct protocol driven DS shipping studies, use existing studies or provide other documented evidence to demonstrate that the DS can be transferred from the DS manufacturing site to the Drug Product (DP) manufacturing site using a qualified shipping solution. Drug Substance shipping studies will incorporate the following aspects of shipping: (Note: A grouping strategy may be applied to utilize studies for more than one location.)

- (b) (4)
- [redacted]
- [redacted]
- [redacted]
- [redacted]

1.1.1.1.5. DS Comparability

Analytical comparability of the DS will be performed using lot release tests as well as additional characterization methodology. (b) (4) [redacted]

1.1.1.2. Drug Product (DP)

1.1.1.2.1. Technology Transfer

1.1.1.2.1.1. (b) (4) [redacted]

The DP process will be developed from the (b) (4) [redacted] used to support Ph3 in US, and eventually scaled to (b) (4) [redacted] Activities will focus primarily on:

- (b) (4) [redacted]
- [redacted]
- [redacted]
- [redacted]

The DP process will be (b) (4) [redacted] concurrent with the process development activities. A pre-validation and validation strategy, possibly based on an assessment of control and consistency through critical analytical review, will be developed and discussed with the FDA to align expectations. AstraZeneca shall contract with a third party for DP test and release and to manage all documentation and reporting activities for testing and release of Drug Product. Release testing to ensure safe and efficacious material may include (b) (4) [redacted]

1.1.1.2.1.2. (b) (4) [redacted]

(b) (4) The DP process will be developed from the (b) scale used to support Ph3 in US, and scaled to a (b) (4) Process will be implemented (b) (4) to meet the expected production volume from the site. Activities will focus primarily on the following:

- (b) (4)
-
-
-

A pre-validation and validation strategy, possibly based on an assessment of control and consistency through critical analytical review, will be developed and discussed with the FDA to align expectations. AstraZeneca shall contract with a third party for DP test and release and to manage all documentation and reporting activities for testing and release of Drug Product. Release testing to ensure safe and efficacious material may include (b) (4)

1.1.1.2.1.3. Support for licensure

This proposal includes scope and costs to support the following list of additional studies:

- (b) (4)
-
-
-

Additional data may be required for EUA, BLA approval or as post-marketing commitments during the period of performance of the Other Transactional Agreement. AstraZeneca shall conduct additional studies that would support licensure. If additional work is determined to be necessary by AstraZeneca or required by the USG and regulatory authorities, it may be necessary to modify the scope and assess the financial impact, with changes implemented subject to approval by both parties.

1.1.1.2.2. DP Analytical Method Transfer and Validation

AstraZeneca shall contract to develop Analytical Method Transfer Protocols and Reports. All information related to manufacture, testing and release activities will be delivered to AstraZeneca.

Assays proposed for test and release of DP, DP comparability, and DP stability are specified in Table 1.1.1.2.2-A, Table 1.1.1.2.2-B and Table 1.1.1.2.2-C, respectively.

Table 1.1.1.2.2-A Drug Product Release Tests Planned, As Necessary

Method Description	DP Release
(b) (4)	

(b) (4)	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	

Table 1.1.1.2.2-B Drug Product Comparability Tests Planned, As Necessary

Method
(b) (4)
[redacted]
[redacted]
[redacted]

*Table 1.1.1.2.2-C Drug Product Stability Tests **Planned**, As Necessary*

Method Description	DP Stability
(b) (4)	
[redacted]	
[redacted]	
[redacted]	

1.1.1.2.3. DP Stability

AstraZeneca shall contract to develop a DP Stability Study Plan and to conduct stability testing of DP produced (b) (4) . Drug Product container-closure system(s) will be assessed for stability concurrent. Stability indicating analytical tests will be performed as summarized in Table 1.1.1.2.2-c. (b) (4)
[redacted]

1.1.1.2.4. DP Shipping Studies

In accordance with federal regulations, AstraZeneca shall contract with an established service provider to conduct a protocol driven DP shipping study, use existing studies, or provide other documented evidence to establish the critical and qualified shipping parameters that will be used by external distribution teams in order to ensure successful DP transfer from the manufacturing site to the (b) (4) distribution centers. Drug Product shipping studies will incorporate the following aspects of shipping: (Note: A grouping strategy, worst-case parameter testing or existing studies may be applied to utilize studies for more than one location.)

- (b) (4)
- (b) (4)
- (b) (4)

1.1.1.2.5. DP Comparability

Analytical comparability of the DP will be performed using lot release tests as well as additional characterization methodology. (b) (4)

1.2. Demonstration DS Manufacture (DOD Contract 1 WBS2; BARDA WBS 2)

1.2.1. Manufacture & Release

AstraZeneca shall contract with and oversee the large-scale manufacture (b) (4) of DS at (b) (4) and execute DS quality agreements as is necessary for shipment to (b) (4) (b) (4) for DP manufacture.

AstraZeneca shall oversee review, approval and release of Drug Substance at (b) (4) to ensure that the product meets quality and regulatory compliance requirements. Specifically, AstraZeneca will ensure satisfactory completion of the following by (b) (4)

A. Batch Production Records for Drug Substance
B. Certificates of Analysis

(b) (4) of DS are budgeted. The US Government will directly pay for (b) (4) (b) (4) Furthermore, AstraZeneca will pay directly to (b) (4) its (b) (4) . The balance of costs for (b) (4) will be reimbursed to AstraZeneca through the prototype contract milestones.

(b) (4)

AstraZeneca and the US Government note that (b) (4) [redacted] In the event that the DS produced exceeds the requirements of this contract, it shall be used to produce up to 200M additional doses under Undefinitized Contract Action (UCA) W15QKN-20-C-0067.

1.2.2. Storage/Shipping

(b) (4) [redacted]

AZ will control all material within our quality system and material will not be final released until all testing has been completed and CoA have been issued.

In addition, AstraZeneca shall provide supply chain planning, management and logistics to manage appropriate supply and inventories across all sites to fulfill the 100MM doses to the USG in the agreed timeframes, and supplier management and oversight of (b) (4) [redacted]

1.3. Demonstration DP Manufacture (DOD Contract 1 WBS3; BARDA WBS 3)

1.3.1. Manufacture & Release

AstraZeneca shall secure raw materials, manufacture and release 100,000,000 doses of DP filled into (b) [redacted] ensuring that the product meets quality and regulatory compliance requirements. Test and release will be conducted at subrecipient facilities (b) (4) [redacted] AstraZeneca will ensure satisfactory completion of the following:

A. Manufacturing Batch Production Records for Final Drug Product
B. Certificates of Analysis

(b) (4) [redacted]

1.4. Demonstration DP Pack/Label (DOD Contract 1 WBS4)

1.4.1. Pack/Label

AstraZeneca shall conduct at (b) (4) [redacted] pack and label of final fill finished DP. A targeted inventory of 100MM doses will be prepared. (b) (4) [redacted]

1.4.2. Storage/Shipping

Pallets of finished DP will be stored at 2-8°C according to the terms and conditions specified in Article 16 of the OTA.

1.5. Nonclinical Toxicology (DOD Contract 1 WBS5)

1.5.1. Dose-ranging developmental toxicology (b) (4) [redacted]

(b) (4) [redacted]

(b) (4)

1.5.2. GLP Prenatal / Postnatal Developmental Toxicity Study (b) (4)

(b) (4)

1.6. Phase 3 Clinical Study (Adult) (DOD Contract 1 WBS6)

1.6.1. Generally

AstraZeneca shall conduct a pivotal Phase 3 vaccine efficacy study in 30,000 adults in the US, Peru, and Chile ≥ 18 years of age who are healthy or who have stable chronic diseases, and who are at increased risk for SARS-CoV-2 infection and COVID-19 disease. The study will be designed to provide robust efficacy, safety (assumes a 2 year safety follow-up), tolerability, and immunogenicity data. AstraZeneca will complete a study protocol and have it reviewed by Regulatory Authorities, perform set-up activities, commence study and complete recruitment, analyze the study results and finalize a clinical study report with the goal to submit the data to FDA to seek approval for use of the vaccine in the broader population. The study will include (b) (4) as summarized in the table below. In addition a DSMB will be managed by the NIH. Costs for investigator payments at (b) (4) costs and the DSMB associated with this study will be borne by the US Government.

(b) (4)

1.6.2. Government Enrollment Notifications and Options

AstraZeneca shall notify the Government when it reasonably expects to enroll (b) (4) at (b) (4) sites, and thereafter for each incremental enrollment of (b) (4) at (b) (4) sites.

When AstraZeneca notifies the Government that it reasonably expects to enroll (b) (4) at (b) (4) sites, the parties shall discuss whether there are any scientific or clinical reasons that such additional enrollees would not provide beneficial clinical data (e.g., trial demographics would be inappropriately skewed). If there are such scientific or clinical reasons, as determined by the Government exercising its reasonable and scientific expertise, (i) the Government would not be required to pay the costs associated with the enrollment of such patients, and (ii) AstraZeneca would be permitted to enroll such additional patients at (b) (4) sites at its own cost and expense. If there are no such reasons, the Government would pay the costs of such enrollees as provided in the milestones. For clarity, the Government's decision cannot be based solely on costs; there must be a reasonable and justifiable scientific or clinical reason that warrants the Government's non-payment in respect of such additional enrollees.

When enrollment of 30,000 trial subjects is completed, the Parties shall assess how many patients AstraZeneca enrolled at (b) (4) sites, whether AstraZeneca enrolled fewer (b) (4) at (b) (4) sites and, if so, the extent to which actual enrollment was (b) (4) (the "Patient Shortfall"). (b) (4)

[redacted]

1.7. Phase 2/3 Clinical Study (Pediatric) (DOD Contract 1 WBS7)

AstraZeneca shall conduct a Phase 2/3 vaccine clinical study in an estimated (b) healthy pediatric subjects aged 2 to <17 years. The study will be designed to provide robust safety, immunogenicity data. AstraZeneca will complete a study protocol and have it reviewed by Regulatory Authorities, perform set-up activities, commence study and complete recruitment, analyze the study results and finalize a clinical study report with the goal to submit the data to FDA to seek approval for use of the vaccine in the pediatric population.

Additional safety studies or risk mitigation efforts may be advisable or required by the FDA in which case they will be proposed as part of the scope and budget for this option if needed.

AstraZeneca must receive written authorization from the Agreements Officer prior to performance on this SOW Section. The technical requirements of this section and associated payment milestones are based on the facts and circumstances that are/were known at the time of base agreement award. It is anticipated that these requirements may need to be revised prior to actual performance. Prior to any Contractor performance pursuant to this section of the Statement of Work, technical requirements and milestone payments shall be mutually negotiated.

1.8. HA Authorization/Approval (DOD Contract 1 WBS8)

1.8.1. IND

AstraZeneca shall prepare and submit a pre-IND meeting request and briefing document with a request for expedited feedback on Phase 3 enabling questions. FDA has indicated that written feedback will be provided and that there will be an opportunity for a teleconference, if needed, to clarify the written feedback. AstraZeneca will take the Agency's feedback into account in the development and submission of an IND to support the FDA's review of the information and data to support the Phase 3 study initiation.

1.8.2. EUA

AstraZeneca shall support the submission of an Emergency Use Authorization request for the vaccine. Working with the USG, AstraZeneca will seek FDA agreement on the appropriate information and data, including the use of interim Phase 3 clinical data, needed for the preparation and submission of the EUA request.

1.8.3. BLA

AstraZeneca shall prepare and submit a Biologics License Application (BLA). The content of the BLA will be informed by consultations with the FDA on key regulatory questions as required to inform risk to approval and possible mitigations to address risks.

1.8.4. Pharmacovigilance

AstraZeneca will perform pharmacovigilance activities according to US and Rest of World (ROW) clinical study and post authorisation regulatory requirements as of 15 September 2020. In the event of new regulatory requirements being implemented, the pharmacovigilance strategy and budget would be assessed for

adequacy. This will include the collection, evaluation and reporting of safety data from both the US and applicable territories in the rest of the world. (b) (4) [redacted]

1.9. Project Management (DOD Contract 1 WBS9)

The Recipient shall provide qualified project management staff to manage the delivery of the scope defined in this proposal, and the project office. The project office will maintain the integrated project schedule and manage deliverables as outlined in Article 17 of this Agreement.

Section G - Contract Administration Data

ACCOUNTING AND APPROPRIATION DATA

AA: 021202120222040000066565425 5 S.0074658.5.27.1 6100.9000021001
COST CODE: A5XAH
AMOUNT: $(b) (4)

AB: 021202120222040000066565425 5 S.0074658.5.27 6100.9000021001
COST CODE: A5XAH
AMOUNT: $(b) (4)

ACRN	CLIN/SLIN	CIN	AMOUNT
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	0003	GFEBS001156717200003	
	0004	GFEBS001156717200004	
	0005	GFEBS001156717200005	
	0006	GFEBS001156717200006	
AB	0007	GFEBS001156717200007	
	0008	GFEBS001156717200008	
	0009	GFEBS001156717200009	
	0010	GFEBS001156717200010	
	0011	GFEBS001156717200011	
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	0028	GFEBS001156717200028	
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	0038	GFEBS001156717200038	
	0039	GFEBS001156717200039	
	0040	GFEBS001156717200040	
	0041	GFEBS001156717200041	
	0042	GFEBS001156717200042	
	0043	GFEBS001156717200043	
	0044	GFEBS001156717200044	

Section H - Special Contract Requirements

TERMS AND CONDITIONS
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ARTICLE 1: BACKGROUND, DEFINITIONS AND SCOPE OF THE AGREEMENT

A. Background

AstraZeneca Pharmaceuticals LP is committed to the clinical evaluation of the efficacy, safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine (now referred to as AZD1222) against SARS-CoV-2, for the prevention of COVID-19 in adults, and for the evaluation of safety and immunogenicity in pediatric populations.

Vaccines are one of the most important public health interventions and provide the most broadly effective and economic approach to prevent wide-spread infectious disease; vaccination is responsible for the global elimination of smallpox, and near elimination of polio. SARS-CoV-2, the virus that causes COVID-19, infects cells using a spike (S) surface glycoprotein which is a perfect target for a protective vaccine that elicits neutralizing antibodies, but its novelty is also a challenge. We are still learning the pathophysiology of the virus and developing a safe and effective vaccine takes time. Many groups are rapidly advancing vaccines for SARS-CoV-2, utilizing a wide range of platforms and approaches (Chen *et al.*, 2020). Virally-vectored vaccines provide a number of advantages (Ewer *et al.*, 2016). These include induction of a strong T-cell response (particularly CD8 T-cells) as well as a strong humoral (antibody) response, intrinsic adjuvanticity, and the potential for a plug and play approach that can leverage significant safety and production/manufacturing information once developed for the vector to accelerate subsequent development with different encoded antigens.

The AZD1222 vaccine developed at, and licensed from, the Jenner Institute at Oxford University, England, consists of the replication-deficient simian adenovirus vector ChAdOx1 (Dicks *et al.*, 2012), modified to express the structural surface glycoprotein (spike protein) antigen of SARS CoV-2. AZD1222 encodes the full-length, codon-optimized coding sequence for the spike protein, derived from genome sequence deposited at GenBank (accession# MN908947). The vaccine also incorporates a tissue plasminogen activator (tPA) signal sequence to drive cell-surface expression, which has been shown to be beneficial in enhancing immunogenicity of another ChAdOx1 vectored CoV vaccine; ChAdOx1 MERS (Alharbi *et al.*,2017).

Chimpanzee adenovirus vaccine vectors have been safely administered to thousands of people, expressing a wide range of infectious disease target antigens. Prior to a current Phase 1/2 in the UK, ChAdOx1 vectored vaccines covering disease targets such as Zika, influenza and malaria have been given to over 320 volunteers with no safety concerns and had been shown to be highly immunogenic at single dose administration (*c.f.*, Antrobus *et al.*, 2014, Wilkie *et al.*, 2020). Of relevance, a single dose of a ChAdOx1 vectored vaccine expressing full-length spike protein from another beta-coronavirus (MERS-CoV) has been shown to induce neutralizing antibodies in a recent human clinical trial (Folegatti *et al.*, 2020).

In preclinical studies, administration of AZD1222 induced a robust immune response resulting in production of neutralizing antibodies in mice and a reduction in SARS-CoV-2 viral load in the bronchoalveolar lavage fluid of non-human primates after viral challenge. Following on to these encouraging results, a Phase 1/2 study in approximately 1000 healthy adults 18-55 years old was initiated (using GMP material generated at Oxford) and has recently completed enrollment in the UK. A Phase 2/3 study to determine the efficacy, safety and immunogenicity of the vaccine in adults $\geqslant$18 years old was initiated on May 30. A Phase 3 study to determine the efficacy, safety and immunogenicity in adults 18-55 years of age was initiated in Brazil on June 23 and in the US on September 1, with plans for additional Phase 3 trials in other parts of the world.

B. Definitions

Agreement Invention: Any invention conceived or first actually reduced to practice in the performance of the Prototype Project under this Agreement.

Agreements Officer or AO: Warranted contracting officer authorized to sign the final OTA for the Government.

Agreement's Officer's Representative or AOR: The individual designated by the Government to monitor all technical aspects and assist in agreement administration of the Prototype Project. The AOR shall only assist in agreement administration of the Prototype Project to the extent delegated such administration authority in writing in the AOR delegation letter by the responsible Agreements Officer.

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

Cause: An event or issue that has been discovered that the Government believes may impact successful performance of the OTA.

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

Date of Completion: The date on which all work is completed or the date on which the period of performance ends.

Definitization: The Agreement on, or determination of, terms, specifications, and price, which converts the undefinitized Agreement to a definitive Agreement.

Deliverable(s): Any documentation (e.g. report, Executive Summary, Letter) given to the Government by AstraZeneca as described in the second column of Table 1 in Article I, Section C.7 under the heading "Deliverable."

Effective Date: The date of execution of this Agreement by the Parties.

Field: The development of the ChAdOx SARS-CoV-2 prophylactic vaccine for the prevention of SARS-CoV-2.

Government: The United States of America, as represented by The Department of Defense and the Department of Health and Human Services.

Government Purpose Rights: 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.

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

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

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

Data or other information for commercial purposes, or (iv) authorize Data or other information to be used by another party.

Party: Each of the Government and AstraZeneca Pharmaceuticals, LP (collectively, "Parties").

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

Program: Prototype efforts being conducted by the Parties pursuant to this Agreement.

Prototype Project: Has the meaning given in Article 1.C.

Project Coordination Team or PCT: Agreements Officer, Agreements Officer's Representative, Subject Matter Experts and Team Leader(s) acting in support of Operation Warp Speed and responsible for periodic and ad-hoc reporting to Operation Warp Speed Leadership.

Property: Any tangible personal property other than property actually consumed during the execution of work under this Agreement.

Recipient: AstraZeneca Pharmaceuticals LP (AstraZeneca or AZ).

Under this Agreement: When used, for example but without limitation, in the definitions of Data, Know-How, Property, and Agreement Inventions, means activities conducted pursuant to this Agreement that are Government funded.

C. Scope of the Agreement

1. **Prototype Project:** The scope of this prototype project is the demonstration by AstraZeneca of the rapid, large scale supply and logistics capability to manufacture and deliver to the Government 100M released and labeled doses, in finished packaging, of the investigational AZD1222 vaccine (the "Prototype Project"). In order to achieve regulatory authorization or licensure and ensure an informed decision as to use of the doses produced under this Prototype Agreement, AstraZeneca will, in parallel, conduct preclinical and clinical evaluation of the AZD1222 vaccine. 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 AZD1222 vaccine. The successful provision of these doses shall establish the effectiveness of a technology capable of potentially providing immediate and long-term solutions to COVID-19 infections.
2. This effort further 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 vaccination of the U.S. population. A detailed description of the specific activities supported by this Prototype Agreement is provided in the Statement of Work, Appendix C (the "Statement of Work").
3. **Associated Production:** It is the intention of the Parties to simultaneously enter into a separate, but associated, sole-source FAR-based contract for the continued production of 200 million doses of AZD1222. Subject to applicable law and regulation, the Parties shall take all steps necessary to negotiate and enter into such a FAR-based contract in good faith with the intent of promptly signing such FAR-based contract as soon as possible after this Agreement.
4. **Performance by Affiliates:** The Government acknowledges and agrees that Recipient may perform its obligations under this Agreement through one or more of its affiliates, provided that Recipient 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.

5. **Reporting:** The Government will have continuous involvement with AstraZeneca throughout the duration of the Period of Performance. The Government will also obtain access to research results and certain technical data rights according to the Deliverables Table (Table 1). In addition, reporting from AstraZeneca to the Government will include the following concerning AZD1222 (required components detailed in Article 17):
    - Weekly Teleconferences
    - Monthly and Annual Technical and Business Reports
    - Draft and Final Technical and Business Reports
    - FDA meetings, submissions, correspondence and audits
    - Daily check-in, as reasonably requested by the AZD1222 PCT
    - Critical programmatic concerns, issues or probable risks that are likely to impact project schedule/cost/performance
    - Technical documents relevant to the performance of activities within scope of this Prototype Agreement
    - Clinical and Operations dashboard
    - Supply chain resiliency, including recipient locations
    - Weekly Production Updates/Dose Tracker
    - Draft and Final Non clinical and Clinical Study Protocols
    - Interim and Final Non clinical and Clinical Study Reports
    - Recipient audits of sub-agreement holders' facilities

6. **Audits:** Until such time as all doses have been delivered under this Agreement, and in no event after expiration of the Period of Performance, audits under this Prototype Agreement may include Government Quality Assurance audits – periodic, *ad hoc* or for cause – of AstraZeneca or sub-agreement holders' facilities included in the AZD1222 supply chain. The Government will provide notification of a periodic or *ad hoc* audit at least (b) (4) prior to the intended audit date and both parties will work in good faith to accommodate the audit and determine scheduling. Audits performed for cause will not require notification by the Government. In all audits, the Government will comply with the Person in Plant requirements set forth in Article 1.C.7.
7. **Person in Plant:** The Government may request to have a government representative in place at Recipient's facility, with no fewer than (b) (4) advance notice of the desired date for that person to be in place. The name, role, scope and duration will be mutually agreed between the Parties in writing in advance. The Government representative will adhere to the agreed scope and to the Recipient's policies, procedures and instructions at all times. As determined by federal law, no Government representative shall publish, divulge, disclose, or make known in any manner, or to any extent not authorized by law, any information coming to him in the course of employment or official duties, while stationed in a Recipient plant.
   If considered for cause, the Government may place representatives in place at Recipient's facility, with no fewer than (b) (4) advance notice of the desired date for the person(s) to be in place, subject to applicable COVID protocols. The names, roles, scope, and duration will be provided to the Recipient in advance. The Government representative will adhere to the Recipient's policies, procedures and instructions regarding facility regulations at all times. As determined by federal law, no Government representative shall publish, divulge, disclose, or make known in any manner, or to any extent not authorized by law, any information coming to him in the course of employment or official duties, while stationed in a Recipient plant.
8. **Deliverables:** Deliverables under this Agreement are listed in Table 1.
9. **Milestones:** Payable milestones under this Agreement are listed in Table 2.

10. **Delivery Schedule:** AstraZeneca will use its best efforts to deliver 100M doses by (b) (4) The foregoing delivery schedule is AstraZeneca's best projection of its manufacturing capability based on (i) the facts and circumstances as they are known to AstraZeneca on the Effective Date and (ii) the planning assumptions shared with BARDA, including but not limited to the assumptions listed below:

The Parties acknowledge that the clinical development schedule is subject to certain factors outside AstraZeneca's control (e.g., actions taken by FDA) and that manufacturing scale-up is being progressed simultaneously with establishment of the supply chain. AstraZeneca will keep the Government apprised of clinical development and manufacturing progress as set forth in Article 17 of this Agreement, and to the extent any changes in circumstances necessitate a revision to the delivery schedule, will notify the Government as soon as reasonably practicable.

In addition, AstraZeneca shall notify the Government promptly upon manufacture and release of the first (b) (4) DS batches and shall provide, in writing, AstraZeneca's latest estimate of drug substance and drug product yield for subsequent doses (the "Manufacturing Report"). Following the Government's receipt of the Manufacturing Report, the Government and AstraZeneca shall discuss the report in good faith and adjust the foregoing delivery schedule as appropriate.

Table 1: Deliverables

#	Deliverable	Due Date	Format	Data Rights
01	Provision of PL 115-92 Letter	(b) (4)	n/a	(b) (4)
02	(b) Production Updates / Dose Tracker		Template to be provided by AOR	
03	(b) (4) Technical and Business Reports, including Risk Management Plan		AstraZeneca-determined format, consistent with Article 17	
04	Draft and Final Nonclinical and Clinical Study Protocols		AstraZeneca-determined format, consistent with Article 17	
05	Interim and Final Nonclinical and Clinical Study Reports		AstraZeneca-determined format, consistent with Article 17	
06	Draft and Final Technical Reports		AstraZeneca-determined format, consistent with Article 17	
07	EUA Filing		AstraZeneca-determined format	
08	BLA Filing		AstraZeneca-determined format	
09	Manufacturing Development Plan[2]		AstraZeneca-determined format	
10	Quality Management Plan[3]		AstraZeneca-determined format	
11	Shipping Specifications and Details[4]		AstraZeneca-determined format	
12	Delivery of 100M doses AZD1222		n/a	
13	Release documentation for doses to be delivered		AstraZeneca-determined format	
14	Security Plan		AstraZeneca-determined format, consistent with Operation Warp Speed OPSEC Requirements (Appendix B)	
15	Supply Chain Resiliency Plan			
16	Manufacturing Data Requirements			
17	Product Development Source Material and Manufacturing Reports			
18	Recipient Locations			

[1] **PL 115-92 Authorization Letter.** 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.

[2] **Manufacturing Development Plan.** AstraZeneca will, in the level of detail and format that AstraZeneca solely elects (provided such format provides a reasonable and industry-standard level of detail), describe the manufacturing process for the vaccine product to ensure conformity with §501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21 United States Code ("U.S.C.") §351 (a)(2)(B)), regarding GMP. This plan shall describe as such information becomes available to AstraZeneca, but is not limited to, (b) (4)

[3] **Quality Management Plan.** AstraZeneca will, in the level of detail and format that AstraZeneca solely elects (provided such format provides a reasonable and industry-standard level of detail), provide a quality management plan for clinical and manufacturing efforts which may include, but is not limited to, (b) (4)

[redacted]

[4] **Shipping Specifications and Details.** In coordination with the Government, Recipient will conduct a single demonstration of the vaccine shipping process prior to the first delivery of doses at a time and in a manner mutually agreed by the Parties. As set forth in the Deliverables Table above, Recipient agrees to share specifications and details associated with the shipping process and containers to enable the Government to adequately plan and prepare for potential distribution of the vaccine. For clarity, this shipping demonstration will not include the shipping of actual released vaccine product.

Table 2: Payable Milestones

Milestone Number	Milestone	Estimated Completion	Determinant of Successful Completion	Budget
1	Contract signature	(b) (4)	n/a	(b) (4)
2	DS (b) (4)		Batch Record or Certificate of Analysis	
3	DP (b) (4)		Certificate of Analysis	
4	(b) (4) of commercial scale DS (GMP or non-GMP)		Batch Records (non-GMP) or Certificates of Analysis (GMP)	
5	1151RM Prelim DART study report		Draft Report	
6	(b) (4)		Enrollment Tracker	
7	(b) (4)		Enrollment Tracker	
8	(b) (4)		Enrollment Tracker	
9	(b) (4)		Enrollment Tracker	
10	(b) (4) of commercial scale DS (GMP or non-GMP)		Batch Records (non-GMP) or Certificates of Analysis (GMP)	
11	DP Validation Report		Validation Report	
12	DS Validation Report		Validation Report	
13	(b) (4)		AO Approval per the terms of the SOW, Section 1.8.4 (Pharmacovigilance)	
14	(b) (4) of commercial scale DS (GMP or non-GMP)		Batch Records (non-GMP) or Certificates of Analysis (GMP)	
15	Deliver (b) (4) Doses FP to (b)	See Article 1.C.10	AO Acceptance per Article 16	
16	Deliver (b) (4) Doses FP to (b)	See Article 1.C.10	AO Acceptance per Article 16	
17a	Deliver (b) (4) Doses FP to (b) (4) (b) (4)	See Article 1.C.10	AO Acceptance per Article 16	
17b	Pharmacovigilance	Concurrent with Milestone 17a	AO Acceptance of Milestone 17a	
18a	Deliver (b) (4) Doses FP to (b) (4) (b) (4)	See Article 1.C.10	AO Acceptance per Article 16	
18b	Pharmacovigilance	Concurrent with Milestone 18a	AO Acceptance of Milestone 18a	
19	Pediatric Phase 3 Study (ROM)	(b) (4)	TBD	
20	BLA Submission		BLA Filing	
21	Phase 3 LSLV		Enrollment Tracker	
22	Ph3 Final CSR		Final CSR (includes safety follow-up)	
23	(b) (4) enrollment of (b) (DOD Approval of (b) patient increment)		AO Approval	
24	(b) (4) enrollment of (b) (DOD Approval of (b) patient increment)		AO Approval	

25	(b) (4) enrollment of (b) (b) patient increment)	(DOD Approval of	(b) (4)	AO Approval	(b) (4)
26	(b) (4) enrollment of (b) (b) patient increment)	(DOD Approval of		AO Approval	
27	(b) (4) enrollment of (b) (b) patient increment)	(DOD Approval of		AO Approval	
28	(b) (4) enrollment of (b) (b) patient increment)	(DOD Approval of		AO Approval	
29	(b) (4) enrollment of (b) (b) patient increment)	(DOD Approval of		AO Approval	
30	(b) (4) enrollment of (b) (b) patient increment)	(DOD Approval of		AO Approval	
31	(b) (4) enrollment of (b) (b) patient increment)	(DOD Approval of		AO Approval	
32	(b) (4) enrollment of (b) (b) patient increment)	(DOD Approval of		AO Approval	
33	(b) (4) enrollment of (b) (b) patient increment)	(DOD Approval of		AO Approval	
34	(b) (4) enrollment of (b) (b) patient increment)	(DOD Approval of		AO Approval	
35	(b) (4) enrollment of (b) (b) patient increment)	(DOD Approval of		AO Approval	
36	(b) (4) enrollment of (b) (b) patient increment)	(DOD Approval of		AO Approval	
37	(b) (4) enrollment of (b) (b) patient increment)	(DOD Approval of		AO Approval	
38	(b) (4) enrollment of (b) (b) patient increment)	(DOD Approval of		AO Approval	
39	(b) (4) enrollment of (b) (b) patient increment)	(DOD Approval of		AO Approval	
40	(b) (4) enrollment of (b) (b) patient increment)	(DOD Approval of		AO Approval	
41	(b) (4) enrollment of (b) (b) patient increment)	(DOD Approval of		AO Approval	
42	(b) (4) enrollment of (b) (b) patient increment)	(DOD Approval of		AO Approval	
43	End of Contract			n/a	n/a
Total					**$1,208,933,813.79**

ARTICLE 2: TERM AND TERMINATION

A. Term of this Agreement

The period of performance for this Prototype Agreement is from the date of award through December 31, 2023 (the "Period of Performance").

B. Rights of Termination

1. The Government will have unilateral right to terminate this agreement upon any one or more of the following events:

   a. (b) (4)

b. The Recipient's Phase 3 clinical trial is terminated prior to completion for safety or efficacy reasons by the Food and Drug Administration;

c. (b) (4)

d. AZ discontinues development due to emerging safety or efficacy data; or

e. (b) (4)

2. With the exception of item "e" above, if the Government exercises its right to terminate based on any of these events, the termination will be effective immediately upon notification to the Recipient. (b) (4)

3. For purposes of a termination under item "e" above, (b) (4)

Milestone Number	Milestone	Budget
1	Contract signature	(b) (4)
2	DS (b) (4) (b) (4)	
3	DP (b) (4)	
4	(b) (4) of commercial scale DS (GMP or non-GMP)	
5	1151RM Prelim DART study report	
10	(b) (4) of commercial scale DS (GMP or non-GMP)	
11	DP Validation Report	
12	DS Validation Report	
Total		

4. Recipient shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. The terms of Article 2 do not give the Government any right to audit the Recipient's records.

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

6. The Government and the Recipient 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 animals and materials

acquired for research use. Failure of the Parties to agree to a reasonable adjustment will be resolved pursuant to Article 7, 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 Program except as otherwise specified herein. For clarity, the Recipient may choose to continue clinical trials following termination, in accordance with patient safety, other ethical considerations and Applicable Law, which trials would be continued at Recipient's cost and expense. To the extent the Recipient chooses not to continue any such trials, Recipient will wind-down the trials to the extent permissible in accordance with patient safety, other ethical considerations, and Applicable Law, which trials would be wound-down at the Government's cost and expense.

C. Stop Work Orders.

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

D. Extension of Term

The Parties may extend by mutual written agreement the Period of Performance if funding availability and research and development opportunities reasonably warrant.

ARTICLE 3: PROJECT MANAGEMENT AND MODIFICATIONS

Technical and project management of the manufacture and delivery of up to 100 million doses of AZD1222 ("Prototype") and associated scope within the Statement of Work shall be managed as detailed in this Article.

A. Project Governance. AstraZeneca is responsible for the overall management of the Prototype Project and related decisions. The Government and AstraZeneca are bound to each other by a duty of good faith in achieving the Prototype Project as defined in Article 1. As such, the Government will have continuous involvement with AstraZeneca. AstraZeneca shall provide project results in accordance with the Deliverables schedule identified in Table 1.

B. Project Management. AstraZeneca and the Government will each designate an individual responsible for facilitating the communications, reporting, and meetings between the Parties. For AstraZeneca the individual will serve as PM, and for the Government the individual will be the AOR.

C. Project Reviews. AstraZeneca and the Government will hold periodic project review meetings as determined by the AstraZeneca Project Manager and AOR, however, these meetings shall not occur more frequently than every (b) (4) .

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

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

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

G. Agreement Administration

Government Points of Contact:

AO

NAME: (b) (6)
MAILING ADDRESS: Bldg 10, Phipps Road, Picatinny Arsenal, NJ, 07806
EMAIL: (b) (6)
PHONE: (b) (6)
AGENCY NAME/DIVISION/SECTION: CCNJ-IC

NAME: (b) (6)
MAILING ADDRESS: Bldg 10, Phipps Road, Picatinny Arsenal, NJ, 07806
EMAIL (b) (6)
PHONE: (b) (6)
AGENCY NAME/DIVISION/SECTION: CCNJ-IC

AOR

NAME: (b) (6)
MAILING ADDRESS: 200 C St SW, Washington DC 20024
EMAIL (b) (6)
PHONE: (b) (6)
AGENCY NAME/DIVISION/SECTION: HHS/ASPR/BARDA

AstraZeneca Points of Contact:

CLM

NAME:
MAILING ADDRESS:
EMAIL:
PHONE:

PM

NAME
MAILING ADDRESS:
EMAIL:
PHONE:

ARTICLE 4: MANAGEMENT OF THE PROJECT

A. Document Review

The Recipient shall provide the PCT sufficient opportunity to review study protocols, reports, daily enrollment and demographic clinical data, and regulatory correspondence. PCT's comments on these documents will be viewed as advisory in nature.

B. Sub-agreement Holders

1. (b) (4)

(b) (4) [redacted]

2. For clarity, as detailed within the Articles themselves, the following Articles require flow-down to sub-agreements/contracts (b) (4) [redacted]

(b) (4) [redacted]

ARTICLE 5: "PREP ACT" COVERAGE

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

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

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

Therefore, in accordance with Sections IV and VII of the PREP Act Declaration, as well as the PREP Act (42 U.S.C. § 247d-6d), the Department of Defense contracting via assisted acquisition on behalf of the HHS, expressly acknowledges and agrees that the HHS Declaration cited above, specifically its language providing immunity from suit and liability is applicable to this Agreement, as long as AstraZeneca'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 7, "Disputes."

ARTICLE 6: OBLIGATION AND PAYMENT

A. Obligation

1. Except as specified in Article V: Disputes, the Government's liability to make payments to the Recipient is limited only to those funds obligated under this Agreement or by modification to the Agreement. The ACC-NJ Contracting Activity may incrementally fund this Agreement. If modification becomes necessary in performance of this Agreement, pursuant to Article 3 of this Agreement, the AO and the Recipient shall establish and execute a mutually agreed upon revised Schedule of Payable Milestones consistent with the current SOW.

B. Payments

(b) (4) [redacted]

2. After accomplishment of each milestone, the Recipient will submit the corresponding invoice through a Government provided invoicing and payment system, as detailed in Article 18.

(b) (4) [redacted]

4. Payments will be made by the cognizant Defense Finance and Accounting Services office, as indicated below, in accordance with the Prompt Payment Act. Article 18 details how to submit and process invoices.

5. Payments shall be made in the amounts set forth in the SOW, provided the AOR has verified the completion of the applicable milestones. The Government will pay AstraZeneca in US dollars.

6. (b) (4) [redacted]

[redacted]

(b) (4) [redacted]

7. (b) (4) [redacted]

C. Comptroller Access Financial Records and Reports:

AstraZeneca shall maintain adequate records to account for Federal funds received under this Agreement and shall maintain adequate records to account for funding provided under this Agreement. AstraZeneca relevant financial records are subject to examination or audit by or on behalf of the Comptroller General, Contracting Activity AO, or other Government Official for a period not to exceed three (3) years after expiration of the term of the Agreement. The Comptroller General, AO or designee shall have direct access to sufficient records and information of any party to this agreement or any entity that participates in the performance of this agreement to ensure full accountability for all funding under this Agreement. Such audit, examination or access shall be performed during business hours on business days upon prior written notice and shall be subject to the security requirements of the audited party. Any audit required during the course of the program may be conducted by the Comptroller General or other Government Official using Government auditors or, at the request of Recipient's external CPA accounting firm at the expense of the Recipient.

1. Lower Tier Agreements

The Performer shall include this Article, suitably modified to identify the Parties, in all subcontracts or lower tier agreements entered into solely in connection with this Agreement.

ARTICLE 7: DISPUTES

A. General

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

B. Dispute Resolution Procedures

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

2. Whenever legal disputes or claims arise, the Parties shall attempt to resolve the issue(s) by discussion and come to mutual agreement on a resolution as soon as practicable. In no event shall a dispute, disagreement or misunderstanding that arose more than six (6) months prior to the

notification made under sub-section B.3 of this Article constitute the basis for relief under this Article unless one level above the AO, in the interests of justice, waives this requirement.

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

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

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

C. Limitation of Damages

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 obligated as of the time the dispute arises, except with respect to violations of Articles 5, 8, 9, or 10 of this Agreement.

ARTICLE 8: 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 Recipient may, by mutual consent, identify elsewhere in this Agreement specific information and/or categories of information which the Government will furnish to the Recipient or that the Recipient is expected to generate which is confidential. Similarly, the Agreements Officer and the Recipient may, by mutual consent, identify such Confidential Information from time to time during the Period of Performance. 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 Recipient 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. The Receiving Party shall not directly or indirectly, divulge or reveal to any person or entity any Confidential Information of another Party without the Disclosing Party's prior written consent, or use such Confidential Information except as permitted under this Agreement. Confidential Information shall be subject to the same prohibitions on disclosure as provided for under FAR Part 24.202. Further, any reproduction of Confidential Information or portions thereof that is disseminated within the Government or AstraZeneca, shall be shared strictly on a need to know basis for the purposes of this Agreement and is subject to the restrictions of this provision. In addition to the above, Confidential Information is subject to the protections of the Trade Secrets Act as well as any other remedies available under this Agreement or the law.

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

F. Whenever the Recipient 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 Recipient shall obtain a written determination from the Agreements Officer prior to any release, disclosure, dissemination, or publication.

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

H. The provisions of paragraph (D) of this Article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

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

Subject to Article 4.B, all above requirements MUST be passed to all Sub-awards.

ARTICLE 9: INTELLECTUAL PROPERTY RIGHTS

A. (b) (4) [redacted]

B. **Background IP and Materials.** Recipient 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. (b) (4) [redacted]

D. **Government's Background IP.** The Government warrants that it has no Background IP and therefore lists "None" in Appendix A.

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

F. **Patent Applications.** Each Party shall report any Agreement Inventions to the other Party within 60 days of the time the inventor discloses it in writing to its personnel responsible for patent matters. 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 patent applications 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, 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.** Recipient agrees to take responsibility for the preparation, filing, prosecution, and maintenance of any and all patents and patent applications listed as Recipient Background IP that are relevant to the work performed under this Agreement. Recipient shall keep the Government reasonably advised on the status of Recipient Background IP by providing an annual report on the status of Recipient Background IP. With respect to a Sole Recipient Agreement Invention or a Joint Agreement Invention, prior to acting on a decision by Recipient to abandon or not file in any country a patent or patent application covering a Sole Recipient Agreement Invention or a Joint Agreement Invention, Recipient shall so inform the Government in a timely manner to allow Recipient to thoughtfully consider the Government's comments regarding such a proposed decision.

(b) (4) [redacted]

(b) (4) [redacted]

H. **Patent Enforcement.** Recipient will have the first option to enforce any patent rights covering a Joint Agreement Invention at Recipient's expense. If Recipient chooses not to exercise this option, the Government may enforce patent rights covering a Joint Agreement Invention.

I. Licenses.

Background IP. No Government funding was used to finance the Background IP identified in Appendix A. Therefore, Recipient does not grant to the Government any license to the Background IP identified in Appendix A.

Agreement Inventions. Any Sole Recipient 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 10: DATA RIGHTS

A. Background Data. "Background Data" shall mean all technical data, as defined in 22 C.F.R. § 120.10, that exists prior to execution of this Agreement, or are developed outside the scope of this Agreement. Recipient's Background Data includes, but is not limited to, the following technical data, to the extent such data exists prior to execution of this Agreement or is developed outside the scope of this Agreement:

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 Recipient in the performance of this Agreement, other Recipient materials or Recipient confidential information, whether conducted by the Government or the Recipient (collectively, the "**Subject Data**"), shall be owned by the Recipient. The Parties anticipate that all Subject Data will fall within the deliverables set forth in the Deliverables Table. In the unlikely event that Subject Data is generated that would not be considered a deliverable as provided in the Deliverables Table, all such Subject Data shall be subject to (b) (4) except as otherwise mutually agreed by the Parties. The Recipient agrees to retain and maintain in a clear and readable manner, until seven (7) years after completion or termination of this Agreement, all Subject Data.

C. Marking of Data. The Recipient will mark any Data delivered under this Agreement with the following legend:

"Use, duplication, or disclosure is subject to the restrictions as stated in Agreement No. W15QKN-20-9-1003 between the Government and the Recipient."

Any rights that the Recipient or the Government may have in Data delivered under this Agreement, whether arising under this Agreement or otherwise, will not be affected by Recipient's failure to mark Data pursuant to this Article.

ARTICLE 11: REGULATORY RIGHTS

This Agreement involves research with an investigational biologic that is regulated by the U.S. Food and Drug Administration (FDA) and requires FDA licensure before commercial authorization. It is expected that this contract will result in the FDA authorization, licensure, and commercialization of the AZD1222. The Recipient is the Sponsor of the Regulatory Application (an investigational new drug application (IND), emergency use authorization (EUA), biologics license application (BLA), 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 §§312.50, 600.3(t), the Recipient has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

The Parties agree that Recipient has invested significant time and resources in its platform and IP and is the best company situated to manage production of AZD1222. At the same time, the Parties acknowledge that the Government has made significant investments in the prototype project. Accordingly, the Recipient and the Government agree to the following:

i. **FDA Communications and Engagement.** The Recipient will provide to the Government top-line summaries and key conclusions from all studies supporting the FDA regulatory filing and commercial approval to the extent that such data, summaries, and conclusions are funded by this Agreement. In addition, the Recipient 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 Recipient 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 Recipient will keep the Government apprised of planned FDA meetings and post-meeting outcomes relating to activities funded by this Agreement.

   The Recipient shall provide the Government with all material communications and summaries thereof, both formal and informal, to or from FDA, regarding AZD1222 within 48 hours, and make best efforts to ensure that the Government representatives are invited to participate in any formal or informal Sponsor meetings with FDA. Recipient 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 AZD1222; and (2) notify the FDA that the Government has the right to discuss with FDA any development efforts regarding AZD1222.

ii. **MCM-Related Counterterrorism Legislation.** 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 Recipient recognizes that only the DoD can utilize PL 115-92. As such, the Recipient will work proactively with the Government to leverage this law to its maximum potential under this Agreement. The Recipient shall submit Public Law 115-92 Sponsor Authorization Letter that will be delivered to the designated OWS POC(s) within 30 days of award.

iii. (b) (4) [redacted]

ARTICLE 12: 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 and FDA Good Clinical Practices (GCP) regulations at 21 CFR Part 11, 50, 54 and 56.

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 13: FOREIGN ACCESS TO DATA

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

ARTICLE 14: SCIENTIFIC PUBLICATIONS AND PRESS RELEASES

A. Neither Recipient nor the Government shall make, or permit any person to make, any public announcement concerning the existence, subject matter or terms of this Agreement, the transactions contemplated by it, or the relationship between the Recipient and the Government hereunder, without the prior written consent of the other, such consent not to be unreasonably withheld or delayed, except as required by law, any governmental or regulatory authority (including, without limitation, any relevant securities exchange), any court or other authority of competent jurisdiction.

B. Notwithstanding the foregoing, Recipient and (its upstream licensor) retains the right, but not the obligation, to prepare and submit scientific publications and release information to the public about its COVID-19 development program, without the Government's consent or involvement. The Recipient shall inform the AOR when any 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 Recipient shall not display Government logos including Operating Division or Staff Division logos on any publications.

D. The Recipient 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. Subject to Article 4.B, the Recipient shall include this clause, including this section (d) in all subawards where the sub-agreement holder may propose publishing the results of its work under the subaward. The Recipient shall acknowledge the support of the Government whenever publicizing the work under this Agreement in any written 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. W15QKN-20-9-1003. The US Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon."

ARTICLE 15: ENSURING SUFFICIENT SUPPLY OF THE PRODUCT

A. In recognition of the Government's significant funding for the development and manufacturing of AZD1222 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 AZD1222 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. Recipient gives notice, required to be submitted to the Government no later than 30 business days, following any formal management decision to terminate the product development effort;
ii. Within twenty-four (24) months after the effective date of this Agreement, Recipient, or another entity acting on Recipient'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 AZD1222;
iii. Recipient fails to commercially market AZD1222 within one (1) year after FDA approval, licensure or clearance; or
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.

B. If one or more of the conditions listed in Section 15.A occur, AstraZeneca, upon the request of the Government, subject to the terms of the pre-existing agreement with Licensor, 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 9 and 10 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. (b) (4) [redacted]

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

ARTICLE 16: INSPECTION AND ACCEPTANCE

A. **Delivery and Acceptance**. Recipient shall notify the AO and AOR at least (b) (4) [redacted] prior to initial delivery of AZD1222. Exceptions are permitted if approved by the AO. Upon notification, the AOR will instruct the Recipient (b) (4) [redacted]

(b) (4)

Upon receipt of the provided certificates and any inspection of product at the destination site(s) that was timely requested (b) (4) the AOR will review and recommend acceptance or rejection. The Government shall accept product (b) (4) The AO will correspondingly notify Recipient of acceptance or rejection. However, the Government's acceptance of product will be deemed to have occurred if the Government does not provide written notice of acceptance or rejection within (b) (4) of Recipient's provision of all applicable certificates.

B. **Vendor-managed Inventory**. Product to be stored as VMI (b) (4) (b) (4) and may be stored for a period not longer than (b) (4)

(b) (4) Product held in VMI is subject to the following requirements:

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(b) (4)

Any deviations, out of specification ("**OOS**") results, or other product issues, shall be reported to the USG within (b) (4) of Recipient identification.

C. (b) (4) Product to be shipped to (b) (4) shall be shipped trackable by GPS. Recipient will include the following information on the packing lists provided with (b) (4)

i. Transaction Information (TI)
ii. Transaction History (TH)
iii. Transaction Statement (TS)
iv. Centers for Disease Control (CDC) Purchase Order (PO) Number

The Recipient will also transmit bulk shipment Advance Shipment Notices (ASNs) to CDC via Electronic Data Interchange (EDI).

D. Title and Physical Risk of Loss. (b) (4) [redacted]

E. Risk of Loss Due to Expiry. (b) (4) [redacted]

ARTICLE 17: REPORTING REQUIREMENTS

During the period of performance, the Recipient will be responsible for periodic reporting as summarized in Article 1.C.5 "Reporting" and the Deliverables Table (Table 1). Required components and frequency of such reporting is as follows:

A. Weekly Teleconferences: The Recipient and the AZD1222 Project Coordination Team will participate in teleconferences every week or at the request of the AOR to discuss the performance of the Agreement. The Recipient will provide a proposed agenda by end of day prior to the meeting and will record, maintain and provide draft-meeting minutes to the AOR for review and concurrence within two (2) business days of the teleconference. The AOR will provide feedback within 48 hours of receipt to enable finalization by the Recipient. (For avoidance of doubt, financial information is not expected at these updates, which will be technically focused. AOR reserves the right to include financial personnel in these project meetings, if needed.) Final versions will be submitted to the BARDA eRoom.

On a quarterly basis, at the request of the AOR, the Weekly Teleconference may be expanded in scope to allow for a progress review of the preceding three months and planning for the next three months.

B. Monthly and Annual Technical and Business Reports: The Recipient will submit Monthly Reports to the AOR on the 21st of each month. The Monthly Reports shall provide a concise but comprehensive summary of activities completed during the prior calendar month and the following: updated IMS with activities broken down to WBS Level 4 and an updated Risk Management Plan. The AOR will provide clarification requests or edits to the Recipient within 4 business days, and the Recipient will provide edits or justification to AOR requests. Final versions will be uploaded to the BARDA eRoom.

At 12 month intervals based on award date, an Annual Technical and Business Report will replace the Monthly Technical and Business Report. The format of this report shall be consistent with the Monthly Report and provide a concise but comprehensive summary of activities completed during the prior 12 month period.

C. **Draft and Final Technical Progress Reports:** The Recipient will submit a Draft Technical Progress Report to the AOR no later than (b) (4) prior to the end of the Period of Performance. The draft report will contain a summation of the work performed and results obtained for the entire Period of Performance. The AOR will provide the Recipient with suggested edits and comments within (b) (4) of receipt. In collaboration with the AOR, the Recipient will adjudicate the suggested edits and comments and submit a Final Technical Progress Report on or before the end of the Period of Performance.

D. **FDA meetings, submissions, correspondence and audits:** The Recipient will notify the AOR of all FDA meetings within (b) (4) of receiving a confirmed date and time. For all Type A, B or C FDA meetings, the Recipient will make reasonable effort to ensure that members of the AZD1222 PCT are able to attend as observers (maximum of four individuals). The Parties understand that meetings may be requested by the Agency on an *ad hoc* basis and on a timeline that does not accommodate proper notification. In such instances, the Recipient will make a reasonable effort to notify the AOR in advance of those meetings and, to the extent possible, ensure that members of the AZD1222 PCT are able to attend as observers (maximum of four individuals).

The Recipient will provide the AOR with draft submissions to the FDA at leas(b) (4) prior to submission. The AOR will provide suggested edits and comments to the Recipient within (b) (4) of receipt in order to inform the final submission. The Recipient will either include suggested edits within the final draft, or provide justification for exclusion. The Recipient will make the final submission available to the AOR within (b) (4) of submission to the Agency.

The Recipient will make all official meeting minutes and other correspondence from the Agency available to the AOR within (b) (4) of receipt.

The Recipient will notify the AOR of all scheduled FDA audits within (b) (4) of receiving a confirmed date, time and location. Regarding FDA site visits and audits that are not scheduled in advance, the Recipient will notify the AOR within (b) (4) of the site visit / audit. To the extent feasible, the Recipient will make reasonable effort to ensure that members of the AZD1222 PCT are able to attend daily debriefs as observers (maximum of four individuals).

E. **Daily check-in, as requested by the AZD1222 PCT:** A program specific designee of the Recipient will hold a daily check-in with the AOR or AOR designee to discuss the performance of the Agreement. No agenda, presentation, or official minutes need to be maintained for the regular meeting. The AOR may cancel the daily check-in or substitute a technical or program specific meeting as a replacement. Daily check-ins are expected only during business days.

F. **Confirmed, critical programmatic concerns, issues or probable risks that are likely to impact project schedule/cost/performance:** The Recipient will communicate and document all confirmed programmatic risks to the AOR within (b) (4) of Recipient's awareness. Recipient shall communicate via email or telephone. Following resolution, Recipient will provide all associated deviation reports and corrective and preventative action plans to the AOR within (b) (4) of finalization.

In addition, the Recipient will report to the government any activity or incident that is in violation of established security standards or indicates the loss or theft of government products within (b) (4) of Recipient's awareness of the activity or incident. Recipient will communicate via email, oral or written communication.

G. **Technical documents relevant to the performance of activities within scope of this Prototype Agreement:** Upon request, the Recipient will make the following technical documents available to the AOR:

Process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificates of Analysis and Manufacturing Campaign Reports.

H. **Clinical and Operations Dashboard:** The Recipient shall provide raw clinical data, data analysis, and/or data reports to the AZD1222 PCT. For a daily dashboard, the following will be provided on a daily basis or as requested by the AOR:

1. Recipient will provide data daily as requested in a Government-provided spreadsheet to support a clinical trial dashboard. Recipient and the Government will both work in good faith to ensure data is provided to enable both teams to review the clinical trial(s);
2. Recipient will provide read-only access to IRT and EDC data to two Government representatives;
3. Raw data, tabulation data (e.g., CDISC-compliant SDTM SAS XPT datasets), or data analysis (e.g., CDISC-compliant ADaM SAS XPT datasets) will be provided to the Government upon database freeze(s) and database lock, and at any other times requested by the COR, for the clinical studies supported under this Agreement.

I. **Supply chain resiliency, including recipient locations:** Within (b) (4) of award, the Recipient will provide the AOR with a supply chain resiliency plan. (b) (4)

J. **Dose Tracker:** The Recipient will provide manufacturing reports and manufacturing dose tracking projections/actuals utilizing the "COVID-19 Dose Tracking Templates" or similar. Recipient will update the Dose Tracking Template weekly during manufacturing campaigns and daily during response operations (b) (4) and COVID-19 response, with the first deliverable submission within (b) (4) 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.

K. **Draft and Final Nonclinical and Clinical Study Protocols:** The Recipient will provide Draft Nonclinical and Clinical Protocols to the AOR at least (b) (4) prior to planned submission to the FDA. The AOR will facilitate review of the protocols and provide the Recipient with suggested edits and comments within (b) (4) of receipt. In collaboration with the AOR, the Recipient will adjudicate the suggested edits and comments prior to submission to the FDA.

L. **Interim and Final Nonclinical and Clinical Study Reports:** The Recipient will provide final draft and final Nonclinical and Clinical Study Reports to the AOR within (b) (4) of those reports becoming available to the Recipient. To the extent allowable by law and regulation, the Recipient will also provide Interim Study Reports and/or associated data to the AOR within (b) (4) of availability to the Recipient.

M. **Recipient Audits of Sub-agreement Holders' Facilities:** The Recipient will inform the AOR of upcoming, ongoing, or recent audits/site visits conducted by Recipient of sub-agreement holders as part of the weekly communications, including goals and agenda. The Government reserves the right to participate in the audits. Upon completion of the audit/site visit the Recipient shall provide a report capturing the findings, results and next steps in proceeding with the sub-agreement holder if action is requested by Recipient of the sub-agreement holder to address areas of non-conformance to FDA regulations.

ARTICLE 18: INVOICING AND PAYMENT INSTRUCTIONS

A. Unless otherwise stated, the Recipient is required to utilize the Wide Area Work Flow (WAWF) system when processing invoices and receiving reports under this Agreement. WAWF is a secure web-based system for electronic invoicing, receipt and acceptance. WAWF application enables electronic form submission of invoices, Government inspection, and acceptance documents in order to support DoD's goal of moving to a paperless acquisition process. Authorized DoD users are notified of pending actions by e-mail and are

presented with a collection of documents required to process the contracting or financial action. It uses Public Key Infrastructure (PKI) to electronically bind the digital signature to provide non-reputable proof that the user electronically signed the document with the contents. Benefits include online access and full spectrum view of document status, minimized re-keying and improving data accuracy, eliminating unmatched disbursements and making all documentation required for payment easily accessible. The Recipient shall:

1. Ensure an Electronic Business Point of Contact is designated within the System for Award Management at http://www.sam.gov and
2. Register to use WAWF-RA at the https://piee.eb.mil site. Step-by-step procedures to register are available at the https://piee.eb.mil. **The Recipient is directed to use the "2-N-1" invoice format when processing invoices.**

3. *Inspection/acceptance location*. The Contractor shall select the following inspection/acceptance location(s) in WAWF, as specified by the contracting officer.

ORIGIN / ORIGIN

4. Document routing. The Recipient 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	HQ0338
Issue By DoDAAC	W15QKN
Admin DoDAAC	W15QKN
Inspect By DoDAAC (if applicable)	W56XNH
Ship To Code (if applicable)	W56XNH
Service Approver (DoDAAC)	W56XNH
Service Acceptor (DoDAAC)	W56XNH

B. Payment request and supporting documentation. The Recipient shall ensure a payment request includes appropriate line item and subline item descriptions of the work performed as detailed in the SOW for specific milestones.

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

Agreements Officer: (b) (6) mailto:
Agreements Officer Representative: (b) (6)

E. The Recipient may obtain clarification regarding invoicing in WAWF from the following contracting activity's administrative WAWF point of contact. For technical WAWF help, contact the WAWF help desk at 866-618-5988.

F. The following guidance is provided for invoicing processed under this Agreement through WAWF:

1. The AOR identified in Supplement 4, "Agreement Administration" shall continue to formally inspect and accept the deliverables/milestones. To the maximum extent practicable, the AOR shall review the deliverable(s) milestone report(s) and either:

i. provide a written notice of rejection to the Recipient which includes feedback regarding deficiencies requiring correction or

ii. written notice of acceptance to the AO, and acceptance in the WAWF system.

2. Acceptance within the WAWF system shall be performed by the AOR.

G. Note for DFAS: The Agreement shall be entered into the DFAS system by CLIN - Milestone association (MS)/ACRN as delineated in Section B of the Award. The Agreement is to be paid out by CLIN (MS)/ACRN. Payments shall be made using the CLIN (MS)/ACRN association as delineated at Section B of this Award.

H. Recipient Information: As identified at Central Contractor Registration, i.e., Commercial and Government Entity (CAGE) Code, Dun & Bradstreet number (DUNS), and Tax Identification Number (TIN). Payments shall be made in the amounts set forth in the SOW, provided the AOR has verified the completion of the milestones.

ARTICLE 19: PROHIBITION ON THE USE OF CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT

a) *Definitions.* As used in this clause—

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

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

Covered telecommunications equipment or services means–

(1) Telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities);

(2) For the purpose of public safety, security of Government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities);

(3) Telecommunications or video surveillance services provided by such entities or using such equipment; or

(4) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

Critical technology means–

(1) Defense articles or defense services included on the United States Munitions List set forth in the International Traffic in Arms Regulations under subchapter M of chapter I of title 22, Code of Federal Regulations;

(2) Items included on the Commerce Control List set forth in Supplement No. 1 to part 774 of the Export Administration Regulations under subchapter C of chapter VII of title 15, Code of Federal Regulations, and controlled-

(i) Pursuant to multilateral regimes, including for reasons relating to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology; or

(ii) For reasons relating to regional stability or surreptitious listening;

(3) Specially designed and prepared nuclear equipment, parts and components, materials, software, and technology covered by part 810 of title 10, Code of Federal Regulations (relating to assistance to foreign atomic energy activities);

(4) Nuclear facilities, equipment, and material covered by part 110 of title 10, Code of Federal Regulations (relating to export and import of nuclear equipment and material);

(5) Select agents and toxins covered by part 331 of title 7, Code of Federal Regulations, part 121 of title 9 of such Code, or part 73 of title 42 of such Code; or

(6) Emerging and foundational technologies controlled pursuant to section 1758 of the Export Control Reform Act of 2018 (50 U.S.C. 4817).

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

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

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

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

(b) *Prohibition*.

(1) Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. The Contractor is prohibited from providing to the

Government any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104.

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

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

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

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

(d) *Reporting requirement*

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

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

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

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

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

ARTICLE 20: HEALTH RESOURCES PRIORITIES AND ALLOCATIONS SYSTEMS (HRPAS) PRIORITY RATING

1) This contract shall have a HRPAS priority rating of (b) (4)

2) This is a (b) rated contract for the purpose of emergency preparedness and the Contractor shall follow all the provisions of the HRPAS regulation (45 CFR Part 101). If the Contractor needs to utilize industrial resources to fulfill this rated order for a health resource, it is authorized pursuant to 45 CFR Section 101.36(b) to place the same priority rating and program identification symbol for health resources on its orders for industrial resources with its suppliers.

3) Each rated order executed by AstraZeneca must include the following:

(a) The priority rating: HRPAS (b) (4)

(b) A required delivery date or dates. The words immediately or as soon as possible do not constitute a delivery date;

(c) The written signature on a manually placed order, or the digital signature or name on an electronically placed order, of an individual authorized to sign rated orders for the person placing the order; and

(d) A statement that reads in substance:

(1) This is a rated order certified for national defense use, and you are required to follow all the provisions of the Health Resources Priorities and Allocations System regulation at 45 CFR part 101.

(2) If the rated order is placed in support of emergency preparedness requirements and expedited action is necessary and appropriate to meet these requirements, the following sentences should be added following the statement set forth in paragraph (d)(1) of this section:

i. This rated order is placed for the purpose of emergency preparedness. It must be accepted or rejected within two (2) days after receipt of the order if:

A. The order is issued in response to a hazard that has occurred; or

B. If the order is issued to prepare for an imminent hazard, as specified in HRPAS Section 101.33(e).

Appendix A

Background IP

Government Background IP: None

AstraZeneca Background IP:

(b) (4)

(b) (4)

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Appendix B

STANDARD OWS-SA LANGUAGE FOR DOD OT-BASED CONTRACTS

Supply Chain Resiliency Plan

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

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

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

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

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

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

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

Reports for critical items should include the following information:

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

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

Manufacturing Data Requirements

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

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

Product Development Source Material and Manufacturing Reports and Projections

The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and location and nature of non-clinical and clinical studies sites (it being understood that such information already has been provided).

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

Reporting Procedures and Due Dates:

- Contractor will submit Product Development Source Material Report
  - Within 1 month of contract award
  - Within 30 days of substantive changes are made to sources and/or materials
  - Or on the 6th month contract anniversary.
- Contractor will update the Dose Tracking Template weekly during manufacturing campaigns and daily during response operations (where a Public Health Emergency has been declared) and COVID-19 response, with the first deliverable submission within 15 days of award/modification
- The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission
- If corrective action is recommended, Contractor must address all concerns raised by the Government in writing
- 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.

Contractor Locations

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

Contractor will submit Work Locations Report:

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

Access and General Protection/Security Policy and Procedures

This standard language text is applicable to ALL employees working on critical information related to Operation Warp Speed (OWS) with an area of performance within a Government controlled installation, facility or area. Employees shall comply with applicable installation, facility and area commander installation/facility access and local security

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

Operational Security (OPSEC)

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

Security Plan

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

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

Upon completion of initiating all security measures, the Contractor shall supply to the Contracting Officer a letter (b) (4) [redacted]

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

Security Requirements:

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

Disclosure of Information

Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor,

nor Contractor personnel, shall divulge nor release data nor information obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO in accordance with OWS or other Government policies and/or guidance. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

The Contractor shall comply with all Government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

No information related to data obtained from the Government under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any Government entity for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

Financial Disclosure by Clinical Investigators.

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

Appendix C

Statement of Work

(SEE SECTION C FOR STATEMENT OF WORK)

Section J - List of Documents, Exhibits and Other Attachments

ATTACHMENTS

Attachment 01	PL 115-92 MODEL AUTHORIZATION FOR FDA TO SHARE NON-PUBLIC INFORMATION WITH THE DEPARTMENT OF DEFENSE