SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS

OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, AND 30

1. REQUISITION NUMBER: 0011703423-0001

2. CONTRACT NO.	3. AWARD/EFFECTIVE DATE	4. ORDER NUMBER	5. SOLICITATION NUMBER	6. SOLICITATION ISSUE DATE
W58P0521C0008	24-Sep-2021			

7. FOR SOLICITATION INFORMATION CALL:	a. NAME	b. TELEPHONE NUMBER *(No Collect Calls)*	8. OFFER DUE DATE/LOCAL TIME

9. ISSUED BY CODE W58P05

ACC-APG - COVID RESPONSE - W58P05
6472 INTEGRITY COURT (BUILDING 4401)
ABERDEEN PROVING GROUND MD 21005-3013

TEL:
FAX:

10. THIS ACQUISITION IS
- [X] UNRESTRICTED OR [ ] SET ASIDE: _____ % FOR:
- [ ] SMALL BUSINESS
- [ ] WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM
- [ ] HUBZONE SMALL BUSINESS
- [ ] EDWOSB
- NAICS: 325412
- [ ] SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS
- [ ] 8(A)
- SIZE STANDARD: 1,250

11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED	12. DISCOUNT TERMS	13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	13b. RATING / 14. METHOD OF SOLICITATION
[X] SEE SCHEDULE	Net 30 Days	[ ]	[ ] RFQ [ ] IFB [ ] RFP

15. DELIVER TO CODE

SEE SCHEDULE

16. ADMINISTERED BY CODE

SEE ITEM 9

17a. CONTRACTOR/ OFFEROR CODE 667E9 FACILITY CODE

GLAXOSMITHKLINE LLC
GLAXOSMITHKLINE
(b) (6)
5 MOORE DR RESEARCH TRIANGLE PK
DURHAM NC 27709
TELEPHONE NO.

18a. PAYMENT WILL BE MADE BY CODE HQ0490

DFAS-INDY VP GFEBS
8899 E 56TH STREET
INDIANAPOLIS IN 46249-3800

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

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

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

25. ACCOUNTING AND APPROPRIATION DATA

See Schedule

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

$279,862,800.00

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

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

[X] 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.

REF:

[ ] 29. AWARD OF CONTRACT: REF. OFFER DATED 23-Sep-2021 . YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS: SEE SCHEDULE

30a. SIGNATURE OF OFFEROR/CONTRACTOR

(b) (6)

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

30b. NAME AND TITLE OF SIGNER	30c. DATE SIGNED	31b. NAME OF CONTRACTING OFFICER *(TYPE OR PRINT)*	31c. DATE SIGNED
ROB MACRAE, DIRECTOR GLAXOSMITHKLINE LLC	9/24/2021	TEL: EMAIL:	

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS

OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, AND 30

1. REQUISITION NUMBER	PAGE 1 OF 35
0011703423-0001	

2. CONTRACT NO.	3. AWARD/EFFECTIVE DATE	4. ORDER NUMBER	5. SOLICITATION NUMBER	6. SOLICITATION ISSUE DATE
W58P0521C0008	24-Sep-2021			

7. FOR SOLICITATION INFORMATION CALL:	a. NAME	b. TELEPHONE NUMBER *(No Collect Calls)*	8. OFFER DUE DATE/LOCAL TIME

9. ISSUED BY CODE W58P05

ACC-APG - COVID RESPONSE - W58P05
6472 INTEGRITY COURT (BUILDING 4401)
ABERDEEN PROVING GROUND MD 21005-3013

TEL:
FAX:

10. THIS ACQUISITION IS

- [X] UNRESTRICTED OR [ ] SET ASIDE: _____ % FOR:
- [ ] SMALL BUSINESS
- [ ] WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM
- [ ] HUBZONE SMALL BUSINESS
- [ ] EDWOSB
- NAICS: 325412
- [ ] SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS
- [ ] 8(A)
- SIZE STANDARD: 1,250

11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED

[X] SEE SCHEDULE

12. DISCOUNT TERMS

Net 30 Days

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

13b. RATING

14. METHOD OF SOLICITATION

[ ] RFQ [ ] IFB [ ] RFP

15. DELIVER TO CODE

SEE SCHEDULE

16. ADMINISTERED BY CODE

SEE ITEM 9

17a. CONTRACTOR/ OFFEROR CODE 667E9 FACILITY CODE

GLAXOSMITHKLINE LLC
GLAXOSMITHKLINE
(b) (6)
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8899 E 56TH STREET
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[ ] **17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER**

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

25. ACCOUNTING AND APPROPRIATION DATA

See Schedule

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

$279,862,800.00

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

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

[X] 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.

REF:

[ ] 29. AWARD OF CONTRACT: REF. OFFER DATED 23-Sep-2021 . YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS: SEE SCHEDULE

30a. SIGNATURE OF OFFEROR/CONTRACTOR

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

(b) (6)

30b. NAME AND TITLE OF SIGNER *(TYPE OR PRINT)*	30c. DATE SIGNED	31b. NAME OF CONTRACTING OFFICER *(TYPE OR PRINT)*	31c. DATE SIGNED
		(b) (6) / Contracting Officer/Br. Chief TEL: (b) (6) EMAIL:	24-Sep-2021

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS (CONTINUED)					PAGE 2 OF 35
19. ITEM NO.	20. SCHEDULE OF SUPPLIES/ SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	SEE SCHEDULE				

32a. QUANTITY IN COLUMN 21 HAS BEEN

☐ RECEIVED ☐ INSPECTED ☐ ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED: _____

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

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

33. SHIP NUMBER ☐ PARTIAL ☐ FINAL	34. VOUCHER NUMBER	35. AMOUNT VERIFIED CORRECT FOR	36. PAYMENT ☐ COMPLETE ☐ PARTIAL ☐ FINAL	37. CHECK NUMBER

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

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

Section SF 1449 - CONTINUATION SHEET

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001		(b) (4)	Each	(b) (4)	$279,862,800.00

Sotrovimab
FFP
The contractor shall produce, store and distribute (b) (4) doses of monoclonal antibody (mAb), Sotrovimab IAW the Statement of Work (SOW) and CDRLs (Exhibit A) on this contract.
FOB: Origin (Shipping Point)
PROJECT: COVID-19 CAG
PSC CD: 6505

NET AMT $279,862,800.00

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

ACRN AA @ $279,862,800.00
FFP
PR #0011703423-0001 for (b) (4) doses of monoclonal antibody (mAb), Sotrovimab
PURCHASE REQUEST NUMBER: 0011703423-0001

NET AMT $0.00

ACRN AA $279,862,800.00
CIN: GFEBS001170342300001

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

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

NET AMT

STATEMENT OF WORK

ADDENDUM: The following pages hereby supplements FAR 52.212-4

C.1 Scope: The Department of Defense (DoD) and Department of Health and Human Services (DHHS), in support of the national emergency response to the Coronavirus Disease 2019 (COVID-19), requires the delivery, storage, and distribution of (b) (4) doses of the GlaxoSmithKline (GSK) therapeutic Sotrovimab on a commercial item basis to prevent infection or treat members of the DoD and the general population against the SARS CoV-2 Virus.

C.1.1 Background: The DHHS continuously monitors emerging infectious disease risk and prepares to respond to the threat of novel emerging infectious disease outbreaks in the United States. DHHS is responding to an outbreak of respiratory disease caused by a novel coronavirus that was first detected in China, and which has now spread worldwide, including in the United States. The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (abbreviated "COVID-19").

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a "Public Health Emergency of International Concern" (PHEIC). On January 31, Health and Human Services Secretary Alex M. Azar II declared a Public Health Emergency (PHE) for the United States to aid the nation's healthcare community in responding to COVID-19. On March 11, 2020, the WHO publicly characterized COVID-19 as a pandemic. On March 13, 2020, the President of the United States declared the COVID-19 outbreak a national emergency.

As part of DHHS preparedness and response activities, DHHS seeks to purchase (b) (4) doses of GSK's Sotrovimab (the "product") given FDA emergency use authorization (EUA) on May 20, 2021 (and any associated biologics license application (BLA) subsequently submitted for this product), for delivery on or before November 15, 2021.

C.2 Objectives and Quantity: The contractor shall supply and the Government will purchase (b) (4) doses of the product, as follows:

New Contract under FAR Part 12, Acquisition of Commercial Items: If awarded, the contractor shall supply and the Government will purchase, (b) (4) doses that are delivered to Vendor-Managed Inventory (VMI) by November 19, 2021 (the "Delivery Period"). For clarity, payments will be made for partial deliveries.

Doses: the product, a "dose" of the product means, at the time of contract award, the FDA-authorized (via Emergency Use Authorization) or approved (via Biologics License Application) dose of Sotrovimab for adult

therapeutic use, as identified in the "Treatment" section of the EUA. The Product shall be delivered in a presentation consistent with the FDA approval or authorization.

C.3 Requirements:

C.3.1 Distribution: The contractor shall distribute the product to Government designated administration sites as directed by the Government, EUA authorized or BLA approved finished drug product in vials in accordance with the product's storage and handling requirements in the EUA (and, if granted, the BLA as applicable), including temperature controls. This shall include storage and distribution activities. GSK will engage one or more third party service providers (each a "Distributor") to perform storage and distribution activities for drug product at the direction and on behalf of the Government. The Government will be solely responsible for all allocation determinations related to drug product sold hereunder, including allocation to end users and communication of such allocation determinations to the Distributor. Unless otherwise mutually agreed upon by the parties, drug product shall be shipped to the Government or distributed, as applicable, solely within the United States (including its territories and possessions).The contractor shall be liable for physical risk of loss due to breakage, temperature excursion, or other, until the product is distributed to the Government or the end user (e.g., the hospital, infusion center or other end-user). Unless and until the Government issues a distribution order to GSK, the product purchased and accepted hereunder will be held in vendor managed inventory consistent with the storage conditions required by the FDA EUA (or BLA as applicable) during the period of performance of this contract. To the extent that GSK is responsible for the correction, repair or replacement of Government property held in vendor-managed inventory or in distribution and in the possession of the Distributor, and replacement upon loss or damage is feasible, the Government will accept replacement of such property. Storage and distribution activities shall be supported under this contract through the end of the period of performance. The Government will make every effort to ensure appropriate delivery and utilization of Government purchased product based on clinical need. Prior to the anticipated time of FDA approval of a Biologics License Application ("BLA") for Sotrovimab, the parties will plan and coordinate to ensure efficient and effective distribution of commercial and noncommercial product, including ensuring that the Government's stock of EUA product remains viable and useful during the transition from EUA or BLA. GSK will be required to ensure any doses delivered under EUA are still useful if a BLA is issued by FDA If a BLA is issued during the period of performance, the Government and GSK will work in good faith to ensure that EUA-labeled doses can be utilized for the treatment of COVID-19 patients.

C.3.2 Product Development Manufacturing Reports and Projections: GSK will provide manufacturing reports and manufacturing dose tracking projections/actuals, in the format and having the content mutually agreed upon by the Government and GSK. GSK will update the reports weekly during manufacturing campaigns and upon manufacturing deliverable submission during COVID-19 response operations (where a Public Health Emergency has been declared), with the first deliverable submission within fifteen (15) days of award. For clarity, the reports described in this section apply to Formulated Drug Substance and Drug Product prior to delivery and acceptance by the Government. Tracking reports for product following delivery and acceptance, shall be set forth in the Memorandum of Understanding between GSK, ASPR, and mutually agreed to Distributor(s).

C.4 Reporting: The contractor shall provide the technical reports/deliverables in accordance with Exhibit A, attached to this Statement of Work.

C.5 Period of Performance: The period of performance for this contract is either through May 19, 2022 or delivery of all purchased doses to end users, whichever occurs first.

C.6 Authorized and Approved Uses: Product sold to the Government may be distributed for any indication approved or authorized by the FDA.

C.7 Security

The contractor shall comply with all Countermeasures Acceleration Group Security requirements in Attachment 0001, attached to this Statement of Work, upon final approval of contractor's security plan.

PACKAGING AND MARKING

D.1 Packaging and Marking: The contractor shall label product according to FDA guidance/instructions. Packaging shall be in shipping containers according to the contractor's standard commercial practice.

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

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

TERMS FOR INSPECTION/ACCEPTANCE

E.1 Inspection

The Contracting Officer (KO), the Technical Point of Contact (TPOC) and/or other USG-identified personnel may perform inspection of materials and services. Inspections of material created under this contract may be made by a duly authorized Government representative, and with reasonable notice (i.e., not less than 24 hours). The method of inspection shall be to review the appropriate COA and COC provided by GSK or physically inspect product, as appropriate.

E.2 Acceptance

Notification must be made to the KO and TPOC at least ten (10) calendar days prior to initial delivery. Exceptions are permitted if approved by the KO. The Government shall accept product that conforms to contract requirements based on COA(s) and certificate(s) of cGMP conformity provided by GSK. 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 fourteen (14) calendar days of GSK's provision of all applicable certificates.

Upon acceptance by the TPOC of any lot of Sotrovimab under this contract and confirmation from the KO, title to such Sotrovimab will transfer upon (a) delivery of Sotrovimab to VMI or shipment to a site designated by the Government, and (b) the Government's corresponding written acceptance of each Delivery and Shipment. Storage as VMI may only take place up to six (6) months after initial delivery.

Any deviations, Out Of Specification ("OOS") results, or other product issues, shall be reported to the USG within 3 calendar days after initial delivery. When held in VMI, these materials should be maintained in GSK's or its designated representative's quality and inventory systems. Delivered treatment courses are intended for clinical use, or use under EUA or a BLA.

Upon receipt of the provided COA and COC and any inspection that was timely requested (physical or representative, i.e., pictures), the COR will review and recommend acceptance or rejection. The KO or TPOC will

correspondingly notify GSK of acceptance or rejection of delivery. Payment under this contract will be due for each dose upon acceptance or deemed acceptance and the earlier of delivery to VMI or a Government-designated site.

Upon Delivery of product, notification of delivery quantities and any shipment must be made to the COR and Government representatives.

The Government understands that prices identified in this contract include insurance costs applicable to material that will become Government property, including product stored as VMI. During the term of the contract, GSK will maintain All Risk Property Insurance covering Sotrovimab product held in VMI.

GSK cannot reclaim title to product upon acceptance by the Government. Prior to expiration or termination of this contract, the Government may effect final distribution of any Sotrovimab remaining in storage by any one or a combination of the following methods:

a) The Government may elect to require shipment of the Sotrovimab to US Government facilities in the United States.
b) The Government may direct GSK to destroy all quantities remaining in storage. In this case, a letter of disposition will be provided to the USG.

Any modifications to this acceptance provision for international donations will be specified in Subsection H.13 Donation of Excess Product.

E.3 Vendor-Managed Inventory

Product held in VMI is subject to the following requirements:

a) Provide temperature-controlled storage at the manufacturer's site approved by the Government, according to cGMP and product specifications.
b) Store contract products physically segregated from other products.
c) Ensure proper labeling of stored materials as USG property.
d) Execute stability testing of stored material in a manner consistent with the stability testing plan approved by the Government. Report interim data and results to the Government on a monthly basis.
e) Appropriately identify reserve samples that are representative of drug product, which shall be retained. The reserve samples consist of at least twice the quantity necessary for all tests required to determine whether the drug product meets its established specifications, including a minimum of sixty (60) months of stability testing.
f) Provide the Government access to review the security systems in place and request updates as needed.
g) Include in monthly report inventory for drug product (number of vials), including inventory quantity changes, current quantity, storage facility/location, manufacturing date, latest stability results, date of next expected stability result and the current expiration date (if applicable).
h) Ensure that material being relocated for GSK's convenience is adequately insured at no cost to the Government and with CO approval.
i) Conduct testing necessary to ensure continued use of the stored material for pandemic response.
j) Make appropriate updates to the regulatory documentation, supporting the continued use of the stored material for pandemic response.
k) If using a storage site, provide the quality agreement, specify the location and terms of the storage contract and receive approval by the Government.

Upon request before storage in VMI or, if storage was initially ordered, after storage in VMI, unless otherwise mutually agreed upon by the Parties, product shall be shipped, trackable by GPS, to the Government-designated sites within the continental United States.

GSK will retain physical risk of loss for all product stored as VMI until subsequent shipment to the Government or a Government-designated site. If product is initially shipped to a Government site instead of VMI, risk of loss will transfer upon shipment and acceptance at the Government-designated site. Notwithstanding either of the foregoing sentences, GSK shall not be liable for loss of or damage to supplies caused by the negligence of officers, agents, or employees of the Government acting within the scope of their employment.

GSK will notify the KO and TPOC of any storage or quality deviation for product held in VMI, within 3 calendar days. To the extent that GSK is responsible for the correction, repair or replacement of Government property held in VMI and replacement upon loss or damage is feasible, the Government will accept replacement of such property.

Vendor-managed storage of product manufactured under this contract is supported for up to six (6) months after initial delivery to VMI and, as such, the Government must either (a) take possession on or before the end of this period and provide GSK with disposition instructions in sufficient time to transfer physical material from GSK by this date, or (b) direct GSK to destroy all quantities remaining in storage, or (c) bilaterally modify this contract to extend the period of vendor management of storage prior to this date.

DELIVERY SPECIFICATIONS

	Quantity (vials)	Current Location (9/24/21)	Estimated Date Available at (b) (4) Distribution Center
Shipment A	(b) (4)	(b) (4)	(b) (4)
Shipment B	(b) (4)	(b) (4)	(b) (4)
Shipment C	(b) (4)	(b) (4)	(b) (4)
Shipment D	(b) (4)	(b) (4)	(b) (4)
Total Vials Available	(b) (4)		
(b) (4)			

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
0001	POP 24-SEP-2021 TO 19-MAY-2022	N/A	N/A FOB: Origin (Shipping Point)	
000101	N/A	N/A	N/A	N/A
0002	POP 24-SEP-2021 TO 19-MAY-2022	N/A	JPEO CBRND JOINT COVID-19 RESPONSE (b) (6) 200 C STREET SW WASHINGTON DC 20024 (b) (6) FOB: Destination	W56XNH

CONTRACT ADMINISTRATION

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

G.1 Procuring Contracting Officer:
(b) (6)
ACC Joint COVID-19 Response Division

Contract Specialist:
(b) (6)
ACC Joint COVID-19 Response Division

G.2 GOVERNMENT TECHNICAL POINT OF CONTACT

Health Scientist
(b) (6)
HHS/ASPR/BARDA

G.3 CONTRACTOR'S CONTRACT ADMINISTRATION

(b) (6)
GlaxoSmithKline LLC
5 Moore Drive
Research Triangle Park
Durhham, NC 27709

G.4 PLACES OF PERFORMANCE

GlaxoSmithKline LLC
5 Moore Drive
Research Triangle Park
Durhham, NC 27709

G.5 NOTIFICATION OF REVISIONS AND CHANGE

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

CLAUSES INCORPORATED BY FULL TEXT

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

(a) Definitions. As used in this clause—

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) For fixed price line items—

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

COMBO

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

N/A

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

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

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

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

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

Routing Data Table*

Field Name in WAWF	*Data to be entered in WAWF*
Pay Official DoDAAC	HQ0490
Issue By DoDAAC	W58P05
Admin DoDAAC**	W58P05
Inspect By DoDAAC	W56XNH
Ship To Code	7BM13 – Amerisource Bergen Corporation

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

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

(g) WAWF point of contact.

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

(b) (6) [redacted]

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

(End of clause)

FOR REFERANCE:DFARS PGI 204.7108 Payment Instructions Table
https://www.acq.osd.mil/dpap/dars/pgi/pgi_htm/current/PGI204_71.htm#payment_instructions

ACCOUNTING AND APPROPRIATION DATA

AA: 0212021202220400000664643255 S.0074658.7.4.3 6100.9000021001
COST CODE: A5XAH
AMOUNT: $279,862,800.00

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	000101	GFEBS001170342300001	$279,862,800.00

SPECIAL CONTRACT REQUIREMENTS

H.1 Disclosure of Information:

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

For avoidance of doubt, Controlled Unclassified Information (CUI) within the scope of this contract is limited to details about specific sites or timing and delivery to specific sites. Neither the Contractor nor the Contractor's employees shall disclose CUI which could result in, or increase the likelihood of, the possibility of a break of the activity's security or interrupt the continuity of its operations.

No information related to data obtained under this contract relating to planned, upcoming delivery timing or sites shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions, (b) (4) [redacted] The exceptions identified in this paragraph apply to all disclosure, consent or prior review requirements under Section H except to the extent that a disclosure is otherwise prohibited by law.

H.2 Publication and Publicity

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

(a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each proposed press release or publication addressing delivery

timing or sites to the COR for security review prior to publication. The contractor shall also inform the COR when and how the abstract article or other publication was published, and furnish a copy of the final product.

(b) Unless authorized in writing by the Contracting Officer, the contractor shall not display any DoD logo or seal including Operating Division or Staff Division logos on any publications.

(c) The contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies DoD approval or endorsement of the product(s) or service(s) provided.

(d) The contractor shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract Number W58P05-21-C-0008."

H.3 Confidentiality of Information

Confidential information, as used in this article, means non-public information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

(a) Confidential information, as used in this article, means non-public information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

(b) The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

(c) If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

(d) Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

(e) Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this clause, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

(f) Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.

(g) The provisions of paragraph (H.3.d) of this clause shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

(h) The contractor agrees that sharing of CUI with any third party will mandate that the Contractor's subcontract include provisions of the Countermeasures Acceleration Group OPSEC Security Requirements (reference appendix/attachment/section) relevant to CUI.

H.4 Regulatory Rights

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

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

H.5 Regulatory Compliance

(a) The manufacturing described in the Statement of Work will comply with Current Good Manufacturing Practices (cGMP) regulations at 21 CFR Parts 210 and 211. Production shall occur using cGMP manufacturing process, fully compliant with 21 CFR Parts 210 and 211, for bulk drug substance and fill and finished drug product, with a ramp-up capacity that provides doses sufficient to meet Contractor's obligations under this Agreement.

(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.

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

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

(a) 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;

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

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

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

The Government shall ensure that products or materials provided under this Contract are not used or authorized for

use unless such use occurs in the United States (or a U.S. territory where U.S. law applies such as embassies, military and NATO installations) and is protected from liability under a declaration issued under the PREP Act, or a successor Prep Act declaration of the same or greater scope. Any use where the application of the PREP Act is in question will be discussed with the contractor prior to use and, if the parties disagree on such use, the dispute will be resolved according to the disputes clause of this Contract. The parties acknowledge that items and technology covered by this Contract are being developed for both civil and military applications.

H.7 (b) (4) [redacted]

(b) (4) [redacted]

H.8 Ensuring Sufficient Supply of the Product

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

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

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

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

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

such items:

(a) a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid- up license to practice or have practiced for or on behalf of the U.S. Government any GlaxoSmithKline Background Patent, Copyright, other GlaxoSmithKline Intellectual Property, GlaxoSmithKline Know-How, GlaxoSmithKline Technical Data rights necessary to manufacture doses of the Sotrovimab oral antiviral treatment.

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

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

3. This remedy will remain available until the end of the contract and the license rights and items may only be used by the Government and its contractors to the extent needed to manufacture the number of doses that are not received under this contract, including with respect to any additional orders that are accepted by the contractor after which such licenses granted above shall expire.

H.9 Transportation to Final Destination

During the course of performance under this contract, the Government may require storage of the drug product within the period of performance before delivery to the final location. In these circumstances, the Government will accept Final Drug Product (FDP) at the contractor facility (Origin). The contractor; however, shall continue to be responsible for secure delivery of the therapeutic to its final destination as identified on this contract to the extent requested within the period of performance. Regardless of where acceptance occurs, risk of loss of or damage to supplies shall remain with the contractor until delivery of FDP to the Government or a facility designated by the Government.

H.10 (b) (4) [redacted]

(b) (4) [redacted]

H.11 Buy Back

In the event that the EUA or subsequent approved NDA for Sotrovimab is revoked due to serious safety concerns that were not apparent at the time of contract award, at the Government's request, agrees to buy back from the Government all treatment courses accepted by the Government under this contract that have a remaining shelf life and have yet to be distributed to third parties for administration or to administration sites. Courses that are bought back under this provision will be destroyed. Contractor shall notify the contracting officer immediately upon notification of revocation of the EUA. Contractor shall repurchase the courses within (30) days of the notice at the same price as purchased by the Government unless otherwise agreed.

H.12 EUA Wind-Down

If a BLA is approved by FDA during the term of this Contract for GSK's Sotrovimab, GSK shall ensure that any doses subsequently provided to the Government under this Contract are appropriately labeled and are otherwise suitable for use in the United States under the terms of the EUA (before expiration) or the BLA; provided that the Contractor shall not be required to relabel any doses that are already appropriately labeled under an EUA before seven calendar days after a BLA is approved.

H. 13 Donation of Excess Product

A. In the event the Government determines that doses of Sotrovimab funded under the contract are no longer needed by the Government, the Government may donate remaining doses to any foreign nation (direct or via a non-governmental organization (NGO)) that has an active marketing approval in place for use of Sotrovimab at the time of donation or, if no marketing approval is in place, has an active regulatory authorization and has entered into an indemnification or liability protection, regulatory responsibility, and no-fault compensation agreement with GlaxoSmithKline that covers donated doses and that is satisfactory to GlaxoSmithKline in its sole discretion.

B. The Government shall notify Contractor and shall obtain Contractor's written consent prior to any donation to a foreign nation, including donations through an NGO. Contractor agrees to work with the Government in good faith to ensure all applicable regulatory submissions, import/export permits, and other requirements for donation are completed in advance of shipment to the extent that donation is authorized under this section.

C. GlaxoSmithKline will not be responsible for shipment of Sotrovimab to the receiving foreign nation and shall have no obligation to repackage or relabel the courses already purchased by the USG for delivery to the U.S.market. The Government shall be responsible for obtaining and complying with all applicable regulatory licenses and marketing approvals or authorizations for any donations, resales, or exports. Any such supply of donated product will be subject to (i) prior notification to and approval of the GlaxoSmithKline, not to be unreasonably withheld, and (ii) consistent with Paragraph A, an appropriate agreement being entered into by the applicable recipient pursuant to which GlaxoSmithKline is not subject to, and has appropriate protections, from any liability arising from or connected to the supply, administration, or other use of product in such recipient countries or persons.

D. A list of any donation product will be attached hereto as an Appendix and regularly updated by the contract officer with regard to quantities, countries or NGOs to whom the product is donated. This list will be updated no later than monthly and any record of communication shall contain clear evidence that the parties agreed on the donation.

E. The parties acknowledge that Article H.6 regarding PREP Act coverage does not apply to the provision of any doses under this paragraph to a foreign nation. The USG makes no representations as to PREP Act coverage thereto.

H.14 Subject Inventions Not Expected

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

H.15 Countermeasures Acceleration Group OPSEC Security Requirements

(b) (4) [redacted]

H.16 Period of Performance

In accordance with Statement of Work Section C.5 Period of Performance, the parties agree that the period of performance for this contract is either through May 19, 2022, or delivery of all purchased doses to end users, whichever occurs first. If delivery of all purchased doses to end users occurs prior to May 19, 2022, the contract will be modified by mutual agreement to reflect the actual end date.

H.17 Government Direction for Deliveries

USG direction related to timing, quantity of doses and site of delivery will be provided to GSK and its third party distributor per the terms of a tripartite Memorandum of Understanding which will be established within fourteen calendar days of contract award.

H.18 Advance Understandings

1. (b) (4) [redacted]

2. (b) (4) [redacted]

CLAUSES INCORPORATED BY REFERENCE

52.203-3	Gratuities	APR 1984
52.203-12	Limitation On Payments To Influence Certain Federal Transactions	JUN 2020
52.204-4	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper	MAY 2011
52.204-13	System for Award Management Maintenance	OCT 2018
52.204-18	Commercial and Government Entity Code Maintenance	AUG 2020
52.204-19	Incorporation by Reference of Representations and Certifications.	DEC 2014
52.219-9	Small Business Subcontracting Plan	SEP 2021
52.227-1	Authorization and Consent	JUN 2020
52.227-2	Notice And Assistance Regarding Patent And Copyright Infringement	JUN 2020
52.232-33	Payment by Electronic Funds Transfer--System for Award Management	OCT 2018
52.232-40	Providing Accelerated Payments to Small Business Subcontractors	DEC 2013
52.242-13	Bankruptcy	JUL 1995
52.244-5	Competition In Subcontracting	DEC 1996
252.203-7000	Requirements Relating to Compensation of Former DoD Officials	SEP 2011
252.203-7001	Prohibition On Persons Convicted of Fraud or Other Defense-Contract-Related Felonies	DEC 2008
252.203-7003	Agency Office of the Inspector General	AUG 2019
252.204-7002	Payment For Contract Line or Subline Items Not Separately Priced	APR 2020

252.204-7006	Billing Instructions	OCT 2005
252.204-7012	Safeguarding Covered Defense Information and Cyber Incident Reporting	DEC 2019
252.204-7020	NIST SP 800-171 DoD Assessment Requirements	NOV 2020
252.225-7048	Export-Controlled Items	JUN 2013
252.227-7037	Validation of Restrictive Markings on Technical Data	SEP 2016
252.232-7003	Electronic Submission of Payment Requests and Receiving Reports	DEC 2018
252.232-7010	Levies on Contract Payments	DEC 2006
252.244-7000	Subcontracts for Commercial Items	JAN 2021

CLAUSES INCORPORATED BY FULL TEXT

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

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

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

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

Covered telecommunications equipment or services means--

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

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

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

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

Critical technology means--

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

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

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

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

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

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

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

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

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

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

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

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

(b) Prohibition.

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

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

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

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

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

(d) Reporting requirement.

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

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

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

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

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

(End of clause)

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

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

(b) Assignment. The Contractor or its assignee may assign its rights to receive payment due as a result of performance of this contract to a bank, trust company, or other financing institution, including any Federal lending agency in accordance with the Assignment of Claims Act (31 U.S.C. 3727). However, when a third party makes

payment (e.g., use of the Governmentwide commercial purchase card), the Contractor may not assign its rights to receive payment under this contract.

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

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

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

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

(g) Invoice.

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

(i) Name and address of the Contractor;

(ii) Invoice date and number;

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

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

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

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

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

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

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

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

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

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

Funds Transfer--Other Than System for Award Management), or applicable agency procedures.

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

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

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

(i) Payment.--

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

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

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

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

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

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

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

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

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

(D) Contractor point of contact.

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

(6) Interest.

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

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

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

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

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

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

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

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

(A) The date fixed under this contract.

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

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

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

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

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

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

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

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

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

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

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

purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

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

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

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

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

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

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

(t) Reserved.

(u) Unauthorized Obligations.

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

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

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

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

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

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

(End of Clause)

52.212-5 CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS--COMMERCIAL ITEMS (SEP 2021)

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

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

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

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

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

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

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

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

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

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

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

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

___ (5) [Reserved]

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

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

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

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

____ (10) [Reserved]

____ (11) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (SEP 2021) (15 U.S.C. 657a).

____ (12) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (SEP 2021) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).

____ (13) [Reserved]

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

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

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

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

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

XX (17)(i) 52.219-9, Small Business Subcontracting Plan (SEP 2021) (15 U.S.C. 637(d)(4)).

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

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

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

____ (v) Alternate IV (SEP 2021) of 52.219-9.

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

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

____ (19) 52.219-14, Limitations on Subcontracting (SEP 2021) (15 U.S.C. 657s).

____ (20) 52.219-16, Liquidated Damages—Subcontracting Plan (SEP 2021) (15 U.S.C. 637(d)(4)(F)(i)).

____ (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (SEP 2021) (15 U.S.C. 657f).

XX (22) (i) 52.219-28, Post-Award Small Business Program Rerepresentation (SEP 2021) (15 U.S.C. 632(a)(2)).

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

____ (23) 52.219-29, Notice of Set-Aside for, or Sole-Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (SEP 2021) (15 U.S.C. 637(m)).

____ (24) 52.219-30, Notice of Set-Aside for, or Sole-Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (SEP 2021) (15 U.S.C. 637(m)).

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

____ (26) 52.219-33, Nonmanufacturer Rule (SEP 2021) (15 U.S.C. 657s).

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

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

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

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

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

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

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

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

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

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

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

XX (35)(i) 52.222-50, Combating Trafficking in Persons (OCT 2020) (22 U.S.C. chapter 78 and E.O. 13627).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

____ (48) 52.225-1, Buy American--Supplies (JAN 2021) (41 U.S.C. chapter 83).

____ (49) (i) 52.225-3, Buy American--Free Trade Agreements--Israeli Trade Act (JAN 2021) (41 U.S.C. chapter 83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.

____ (ii) Alternate I (JAN 2021) of 52.225-3.

____ (iii) Alternate II (JAN 2021) of 52.225-3.

____ (iv) Alternate III (JAN 2021) of 52.225-3.

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

XX (51) 52.225-13, Restrictions on Certain Foreign Purchases (FEB 2021) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

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

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

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

____ (55) 52.229-12, Tax on Certain Foreign Procurements (FEB 2021).

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

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

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

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

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

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

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

____ (63)(i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (FEB 2006) (46 U.S.C. 55305 and 10 U.S.C. 2631).

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

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

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

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

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

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

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

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

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

_____ (7) 52.222-55, Minimum Wages Under Executive Order 13658 (NOV 2020) (E.O. 13658).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(xiii) _____ (A) 52.222-50, Combating Trafficking in Persons (OCT 2020) (22 U.S.C. chapter 78 and E.O. 13627).

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

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

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

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

(xvii) 52.222-55, Minimum Wages Under Executive Order 13658 (NOV 2020) (E.O. 13658).

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

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

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

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

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

(xxii) 52.247-64, Preference for Privately-Owned U.S. Flag Commercial Vessels (Feb 2006) (46 U.S.C. 55305 and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

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

(End of clause)

52.252-6 AUTHORIZED DEVIATIONS IN CLAUSES (NOV 2020)

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

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

(End of clause)

252.227-7015 TECHNICAL DATA--COMMERCIAL ITEMS. (FEB 2014)

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

(1) Commercial item does not include commercial computer software.

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

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

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

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

(4) The term item includes components or processes.

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

(b) License. (1) The Government shall have the unrestricted right to use, modify, reproduce, release, perform, display, or disclose technical data, and to permit others to do so, that--

(i) Have been provided to the Government or others without restrictions on use, modification, reproduction, release, or further disclosure other than a release or disclosure resulting from the sale, transfer, or other assignment of interest in the technical data to another party or the sale or transfer of some or all of a business entity or its assets to another party;

(ii) Are form, fit, and function data;

(iii) Are a correction or change to technical data furnished to the Contractor by the Government;

(iv) Are necessary for operation, maintenance, installation, or training (other than detailed manufacturing or process data); or

(v) Have been provided to the Government under a prior contract or licensing agreement through which the Government has acquired the rights to use, modify, reproduce, release, perform, display, or disclose the data without restrictions.

(2) Except as provided in paragraph (b)(1) of this clause, the Government may use, modify, reproduce, release, perform, display, or disclose technical data within the Government only. The Government shall not--

(i) Use the technical data to manufacture additional quantities of the commercial items; or

(ii) Release, perform, display, disclose, or authorize use of the technical data outside the Government without the Contractor's written permission unless a release, disclosure, or permitted use is necessary for emergency repair or overhaul of the commercial items furnished under this contract, or for performance of work by covered Government support contractors.

(3) The Contractor acknowledges that--

(i) Technical data covered by paragraph (b)(2) of this clause are authorized to be released or disclosed to covered Government support contractors;

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

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

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

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

(d) *Release from liability*. The Contractor agrees that the Government, and other persons to whom the Government may have released or disclosed technical data delivered or otherwise furnished under this contract, shall have no liability for any release or disclosure of technical data that are not marked to indicate that such data are licensed data subject to use, modification, reproduction, release, performance, display, or disclosure restrictions.

(e) Applicability to subcontractors or suppliers.

(1) The Contractor shall recognize and protect the rights afforded its subcontractors and suppliers under 10 U.S.C. 2320 and 10 U.S.C. 2321.

(2) Whenever any technical data related to commercial items developed in any part at private expense will be obtained from a subcontractor or supplier for delivery to the Government under this contract, the Contractor shall use this same clause in the subcontract or other contractual instrument, including subcontracts and other contractual instruments for commercial items, and require its subcontractorsor suppliers to do so, without alteration, except to identify the parties. This clause will govern the technical data pertaining to any portion of a commercial item that was developed exclusively at private expense, and the clause at 252.227-7013 will govern the technical data pertaining to any portion of a commercial item that was developed in any part at Government expense.

(End of clause)

LIST OF ATTACHMENTS & EXHIBITS

	Title	# of Pages	Date
Exhibit A	CDRLs	24	24 Sep 2021
Exhibit B	PL 115-92	2	24 Sep 2021
Attachment 0001	Security Requirements	8	24 Sep 2021

Exhibit A
Contract Data Requirements List

Data Item #	Title of Data Item	Date
A0001	Post Award Teleconference	24 Sep 2021
A0002	Kickoff Meeting	24 Sep 2021
A0003	Every 2 Weeks Teleconference	24 Sep 2021
A0004	Quarterly Meetings	24 Sep 2021
A0005	FDA Meetings	24 Sep 2021
A0006	Daily check in with project staff for COVID-19 Contract	24 Sep 2021
A0007	Monthly and Annual Technical Progress Reports and Annual Meeting	24 Sep 2021
A0008	Final Report	24 Sep 2021
A0009	Product Development Source Material and Manufacturing Reports	24 Sep 2021
A0010	Contractor Locations	24 Sep 2021
A0011	Supply Chain and Distribution Tracking	24 Sep 2021
A0012	Distribution Plan	24 Sep 2021
A0013	Distribution Memorandum of Understanding	24 Sep 2021
A0014	Quality Management Plan	24 Sep 2021
A0015	Quality Agreement	24 Sep 2021
A0016	Release documentation for doses to be delivered	24 Sep 2021
A0017	Security Plan	24 Sep 2021
A0018	BARDA Audit	24 Sep 2021
A0019	FDA Audit	24 Sep 2021
A0020	QA Audit	24 Sep 2021
A0021	Incident Report	24 Sep 2021
A0022	FDA Correspondence and Submissions	24 Sep 2021
A0023	Press Releases	24 Sep 2021
A0024	FDA Sharing of Non-Public Information	24 Sep 2021

W58P05-21-C-0008

Exhibit A
Contract Data Requirements List
CDRLs

Date: 24
September 2021
# of pages: 24

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved
OMB No. 0704-0188

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE	17. PRICE GROUP
A0001	Post Award Teleconference	N/A	

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE	18. ESTIMATED TOTAL PRICE
Contractor Format	C.4 Reporting	ASPR BARDA	

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

The contractor shall complete an initial teleconference after contract award

1. Outline activities for the next 30 days
2. Discuss agenda items for the post-award Kickoff Meeting

Frequency

- Within one week of contract award
- Contractor shall provide agenda and establish a teleconference number at least 3 business days in advance of the teleconference unless notified that BARDA will supply one
- TPOC edits/approves and instructs contractor to distribute agenda prior to meeting by at least 2 business days
- Contractor provides meeting minutes to TPOC within 3 business days after the meeting
- TPOC reviews, comments and approves minutes within 10 business days

14. DISTRIBUTION

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		Reg	Repro
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CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

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OMB No. 0704-0188

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE	17. PRICE GROUP
A0002	Kickoff Meeting	N/A	

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE	18. ESTIMATED TOTAL PRICE
Contractor Format	C.4 Reporting	ASPR BARDA	

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

The Contractor shall complete a Kickoff meeting after contract award

Frequency
- Within a month of contract award, pending concurrence by the contracting officer
- Contractor shall provide itinerary and agenda at least 5 business days in advance of site visit or virtual meeting
- TPOC edits/approves and instructs contractor to distribute agenda prior to meeting by at least 3 business days
- Contractor provides meeting minutes to TPOC within 3 business days after the meeting
- TPOC reviews, comments, and approves minutes within 10 business days

14. DISTRIBUTION

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CONTRACT DATA REQUIREMENTS LIST

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A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE	17. PRICE GROUP
A0003	Every 2 weeks Teleconference	N/A	

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE	18. ESTIMATED TOTAL PRICE
Contractor Format	C.4 Reporting	ASPR BARDA	

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

The Contractor shall participate in teleconferences every 2 weeks, with BARDA to discuss the performance on the contract. Meeting frequency can be increased or decreased as needed during the course of the project.

Frequency

- Contractor provides agenda to TPOC no later than 2 business days in advance of meeting. Alternatively, a standing agenda may be used
- TPOC edits/approves and instructs contractor to distribute agenda prior to meeting, unless a standing agenda is used
- Contractor distributes agenda and presentation materials at least 24 hours in advance
- Contractor provides meeting minutes to TPOC within 5 business days of the meeting

14. DISTRIBUTION

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CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved
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A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE	17. PRICE GROUP
A0004	Quarterly Meetings	N/A	

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE	18. ESTIMATED TOTAL PRICE
Contractor Format	C.4 Reporting	ASPR BARDA	

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

At the discretion of the government the Contractor shall hold recurring teleconference. The meetings will be used to discuss contract progress in relation to the Program Management deliverables described below as well as study designs, technical, regulatory, and ethical aspects of the program.

Frequency

- Contractor shall provide itinerary and agenda at least 5 business days, and presentation materials at least 3 business days in advance of site visit
- TPOC edits/approves and instructs contractor to distribute agenda prior to meeting by at least 3 business days
- Contractor provides meeting minutes to TPOC within business days after the meeting
- TPOC reviews, comments, and approves minutes within 10 business days

14. DISTRIBUTION

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A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
A0005	FDA Meetings	N/A

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
Contractor Format	C.4 Reporting	ASPR BARDA

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

16. REMARKS

The contractor shall notify the Government of any meeting scheduled with FDA, include USG attendees in in-person or telecon meetings and provide final minutes of any meeting, to the extent related to Sotrovimab during the period of performance.

Frequency

- Contractor shall notify BARDA of upcoming FDA meeting within 48 hours of the receiving notification from the FDA that a meeting date for the Type A, B or C meeting has been granted OR within 48 hours of after meeting occurrence for ad hoc meetings
- Contractor will include at least 2 USG personnel in the attendee list for meetings with FDA relevant to the work performed under this contract
- The Contractor shall forward FDA-issued preliminary comments and final minutes of any meeting with the FDA to BARDA within 2 calendar business days of receipt

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES		
	Draft	Final	
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ASPR BARDA	1	1	0
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CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

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A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE	17. PRICE GROUP
A0006	Daily check in with project staff for COVID-19 Contract	N/A	

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE	18. ESTIMATED TOTAL PRICE
Contractor Format	C.4 Reporting	ASPR BARDA	

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

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

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

Frequency
- No agenda will be required for the meeting
- No meeting minutes are required
- Contractor will provide bulleted email updates following any call or in lieu of a call by 2PM for that day

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES		
	Draft	Final	
		Reg	Repro
ASPR BARDA	1	1	0
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CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

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A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE	17. PRICE GROUP
A0007	Monthly & Annual Technical Progress Reports/Annual Meeting	N/A	

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE	18. ESTIMATED TOTAL PRICE
Contractor Format	C.4 Reporting	ASPR BARDA	

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

A consolidated submission of all slides and data presented at the biweekly telecons will serve as the monthly report. The report only consists of a summary of quantity of product delivered, when and location of the delivery.

Frequency

• Monthly Reports shall be submitted on the 20th day of the month covering the preceding month; Annual Reports submitted on the 30th calendar day of the month after each contract anniversary. Monthly progress reports are not required for the months when the Annual Report(s) are due, and Monthly/Annual Report(s) are not due during a month when the Final Report (final version, not draft) is due (see CDRL A009). The TPOC and KO will review the monthly reports with the Contractor and provide feedback

• Contractor shall provide FINAL versions of reports within 10 business days after receiving BARDA comments/edits

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES		
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ASPR BARDA	1	1	0
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A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE	17. PRICE GROUP
A0008	Final Report	N/A	

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE	18. ESTIMATED TOTAL PRICE
Contractor Format	C.4 Reporting	ASPR BARDA	

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

Final Report containing a summation of the work performed over the entire contract. At minimum, the Final Report should include total number of doses made available to the USG, total number of doses shipped to point of use and total number of doses remaining in VMI as of the date of the report.

Frequency

- The Final Report shall be submitted 30 calendar days before the end of the PoP or no later than 7 calendar days after final delivery of (b) doses to Government-determined sites.

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES		
	Draft	Final	
		Reg	Repro
ASPR BARDA	1	1	0
CCAP-JCRD			0
15. TOTAL →	1	1	0

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CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

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A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
A0009	Product Development Source Material and Manufacturing Reports and Projections	N/A

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
Contractor Format	C.4 Reporting	ASPR BARDA

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

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

The Contractor will provide manufacturing reports and manufacturing dose tracking projections/actuals, on any contract/agreement that is manufacturing product, including product for clinical trial use.

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

Frequency
• Contractor will submit Product Development Source Material Report
o Within month of contract award or within 30 days of substantive changes are made to sources and/or materials

• Contractor will update the dose tracking projections weekly during manufacturing campaigns and daily during response operations (where a Public Health Emergency has been declared) and COVID-19 response, with the first deliverable submission within 15 days of award/modification. Updates to be provided weekly in advance of commercial-scale manufacturing and daily once material for use in response operations begins manufacture.

• The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission
• If corrrective action is recommended, Contractor must address all concerns raised by BARDA in writing

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES Draft	Final Reg	Final Repro
ASPR BARDA	1	1	0
CCAP-JCRD			0
15. TOTAL →	1	1	0

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
(b) (6) (b) (6)	24 Sep 21	(b) (6) (b) (6)	24SEPT21

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

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OMB No. 0704-0188

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE	17. PRICE GROUP
A0010	Contractor Locations	N/A	

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE	18. ESTIMATED TOTAL PRICE
Contractor Format	C.4 Reporting	ASPR BARDA	

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

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

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

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES		
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		Reg	Repro
ASPR BARDA	1	1	0
CCAP-JCRD			0
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CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

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A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE	17. PRICE GROUP
A0011	Supply Chain and Distribution Tracking	N/A	

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE	18. ESTIMATED TOTAL PRICE
Contractor Format	C.4 Reporting	ASPR BARDA	

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

BARDA and MCM Manufacturers play an important role in the distribution of therapeutics to the American people under a nationwide response. BARDA will work with the manufacturer to monitor what is in the manufacturing pipeline. Contractor will relay final drug product information as it is being released to the BARDA/ASPR. This information will be returned to BARDA, the contractor and distributor. Distributors will use that information to ship therapeutics to sites of administration/end user.

Frequency

Provide the following information in order to coordinate the movement and delivery of product from manufacturing locations to administration/end user:

- Provide a Point of Contact information (name, title, phone, email) for manufacturing / supply chain matters
- Provide therapeutic labeling, packaging and distribution information as soon as it becomes available. At a minimum, include the following, and as applicable:
  - Primary Container Information
  - Number of doses per primary container
  - Unit of Sale (carton, box, package, other)
  - Quantity per Unit of Sale
  - National Drug Code (NDC) or NDC-like code under EUA
  - Unit of Sale dimensions (H,W, L)
  - Unit of Sale weight
  - Intermediate Package
  - Intermediate Package dimensions
  - Intermediate Package weight
  - Quantity Unit of Sale per pallet
  - Storage Requirements
  - Stability Information
- Obtain concurrence on planned shipment protocols prior to transport
- If therapeutic will require ultra-cold storage temperatures at the designated distribution centers, products should be packaged in 100-dose units to facilitate pick/pack process and reduce exposure of workers to ultra-cold temperatures.
- Include the following DSCSA data elements, TI, TH and TS in packing lists.
- Include the contract number on the packing list for all shipments
- Include a copy of the MSDS (with QR code) in the packing list envelope with each shipment.
- Send electronic/scanned copies of all bulk shipment related documents to the TPOC for three-way matching on the day shipment occurs.

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES		
	Draft	Final	
		Reg	Repro
ASPR BARDA	1	1	0
CCAP-JCRD			0
15. TOTAL →	1	1	0

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
(b) (6)	24 Sep 21	(b) (6)	24SEPT21

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved
OMB No. 0704-0188

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE	17. PRICE GROUP
A0012	Distribution Plan	N/A	

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE	18. ESTIMATED TOTAL PRICE
Contractor Format	C.4 Reporting	ASPR BARDA	

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

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

Frequency
Date of submission - Due 60 days after award unless otherwise agreed by the Parties.

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES		
	Draft	Final	
		Reg	Repro
ASPR BARDA	1	1	0
CCAP-JCRD			0
15. TOTAL →	1	1	0

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
(b) (6) (b) (6)	24 Sep 21	(b) (6) (b) (6)	24SEPT21

CONTRACT DATA REQUIREMENTS LIST

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Form Approved
OMB No. 0704-0188

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
A0013	Distribution Memo of Understanding	N/A

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
Contractor Format	C.4 Reporting	ASPR BARDA

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

This document is an understanding between ASPR, contractor, and the distributors to set forth the terms for each party to work together.

Frequency

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

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES		
	Draft	Final	
		Reg	Repro
ASPR BARDA	1	1	0
CCAP-JCRD			0
15. TOTAL →	1	1	0

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
(b) (6) [redacted] (b) (6) [redacted]	24 Sep 21	(b) (6) [redacted] (b) (6) [redacted]	24SEPT21

CONTRACT DATA REQUIREMENTS LIST

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Form Approved
OMB No. 0704-0188

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
A0014	Quality Management Plan	N/A

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
Contractor Format	C.4 Reporting	ASPR BARDA

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

Plan may include, but is not limited to the manufacturing quality policy and objectives, management review, competencies and training, process document control, feedback, evaluation, corrective action and preventive action, process improvement, measurement, and data analysis processes. The framework is normally divided into infrastructure, senior management responsibility, resource management, life-cycle management, and quality management system evaluation.

Frequency
Date of submission - Plan will be delivered electronically within 30 days of contract award to the KO and TPOC.

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES		
	Draft	Final	
		Reg	Repro
ASPR BARDA	1	1	0
CCAP-JCRD			0
15. TOTAL →	1	1	0

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
(b) (6) (b) (6)	24 Sep 21	(b) (6) (b) (6)	24SEPT21

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved
OMB No. 0704-0188

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE	17. PRICE GROUP
A0015	Quality Agreement	N/A	

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE	18. ESTIMATED TOTAL PRICE
Contractor Format	C.4 Reporting	ASPR BARDA	

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

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

Frequency
Date of submission - Agreement will be signed by the USG and the manufacturer within 30 days of contract award. Agreement will be delivered electronically to the KO and TPOC.

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES		
	Draft	Final	
		Reg	Repro
ASPR BARDA	1	1	0
CCAP-JCRD			0
15. TOTAL →	1	1	0

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
(b) (6) (b) (6)	24 Sep 21	(b) (6) (b) (6)	24SEPT21

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved
OMB No. 0704-0188

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
A0016	Release Documentation for Doses to be Delivered	N/A

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
Contractor Format	C.4 Reporting	ASPR BARDA

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

Contractor will deliver Certificate of Analysis and Certificate of Compliance for doses to be delivered.

Frequency
Documentation shall be provided within three business days after being prepared by Contractor.

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES		
	Draft	Final	
		Reg	Repro
ASPR BARDA	1	1	0
CCAP-JCRD			0
15. TOTAL →	1	1	0

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
(b) (6) [redacted] (b) (6) [redacted]	24 Sep 21	(b) (6) [redacted] (b) (6) [redacted]	24SEPT21

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved
OMB No. 0704-0188

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
A0017	Security Plan	N/A

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
Contractor Format	C.4 Reporting	ASPR BARDA

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

(b) (4)

[redacted]

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES		
	Draft	Final	
		Reg	Repro
ASPR BARDA	1	1	0
CCAP-JCRD			0
15. TOTAL →	1	1	0

17. PRICE GROUP	18. ESTIMATED TOTAL PRICE

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
(b) (6) [redacted] (b) (6) [redacted]	24 Sep 21	(b) (6) [redacted] (b) (6) [redacted]	24SEPT21

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved
OMB No. 0704-0188

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE	17. PRICE GROUP
A0018	BARDA Audit	N/A	

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE	18. ESTIMATED TOTAL PRICE
Contractor Format	C.4 Reporting	ASPR BARDA	

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

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

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

Frequency

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

Once corrective action is completed, the Contractor will provide a final report to BARDA

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES Draft	Final Reg	Final Repro
ASPR BARDA	1	1	0
CCAP-JCRD			0
15. TOTAL →	1	1	0

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
(b) (6) (b) (6)	24 Sep 21	(b) (6) (b) (6)	24SEPT21

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved
OMB No. 0704-0188

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE	17. PRICE GROUP
A0019	FDA Audits	N/A	

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE	18. ESTIMATED TOTAL PRICE
Contractor Format	C.4 Reporting	ASPR BARDA	

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

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

Frequency

- Contractor shall notify KO and TPOC within 10 business days of a scheduled FDA audit or within 48 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice
- Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 2 business days of receiving correspondence from the FDA or third party
- Contractor agrees to provide a copy of its response to the FDA in response to an audit report within 2 business days of submission to FDA.

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES Draft	Final Reg	Final Repro
ASPR BARDA	1	1	0
CCAP-JCRD			0
15. TOTAL →	1	1	0

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
(b) (6) [redacted] (b) (6) [redacted]	24 Sep 21	(b) (6) [redacted] (b) (6) [redacted]	24SEPT21

CONTRACT DATA REQUIREMENTS LIST

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Form Approved
OMB No. 0704-0188

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE	17. PRICE GROUP
A0020	QA Audits	N/A	

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE	18. ESTIMATED TOTAL PRICE
Contractor Format	C.4 Reporting	ASPR BARDA	

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

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

Frequency

• Contractor shall notify KO and TPOC a minimum of 10 business days in advance of upcoming, audits/site visits of subcontractors
• Contractor shall provide the TPOC and KO with the Executive Summary and subsequent response TPOC directive/actions if applicable within 5 business days of completion. TPOC and KO will review the report and provide a response to the Contractor with 10 business days

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES		
	Draft	Final	
		Reg	Repro
ASPR BARDA	1	1	0
CCAP-JCRD			0
15. TOTAL →	1	1	0

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
(b) (6) [redacted] (b) (6) [redacted]	24 Sep 21	(b) (6) [redacted] (b) (6) [redacted]	24SEPT21

CONTRACT DATA REQUIREMENTS LIST

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OMB No. 0704-0188

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE	17. PRICE GROUP
A0021	Incident Report	N/A	

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE	18. ESTIMATED TOTAL PRICE
Contractor Format	C.4 Reporting	ASPR BARDA	

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

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

- Due within 48 hours of discovery of activity or incident or within 24 hours discovery of for a security activity or incident
- Email or telephone with written follow-up to TPOC and KO
- Additional updates due to TPOC and KO within 48 hours of additional developments
- Contractor shall submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues

If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by BARDA within 5 business days of receiving such concerns

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES		
	Draft	Final	
		Reg	Repro
ASPR BARDA	1	1	0
CCAP-JCRD			0
15. TOTAL →	1	1	0

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
(b) (6) (b) (6)	24 Sep 21	(b) (6) (b) (6)	24SEPT21

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A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
A0022	FDA Correspondence and Submissions	N/A

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
Contractor Format	C.4 Reporting	ASPR BARDA

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

All submissions and correspondence with potential to directly impact EUA/BLA status of Sotrovimab, EUA/BLA label and/or product insert, delivery schedule to VMI or Government-designated sites, or suitability for human use for any product used to fulfill the delivery requirements of this contract.

Frequency
Material FDA correspondence and final FDA submissions shall be submitted to the TPOC concurrently with submission to the FDA or no later than 2 calendar days of receipt or submission.

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES		
	Draft	Final	
		Reg	Repro
ASPR BARDA	1	1	0
CCAP-JCRD			0
15. TOTAL →	1	1	0

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
(b) (6) (b) (6)	24 Sep 21	(b) (6) (b) (6)	24SEPT21

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved
OMB No. 0704-0188

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER
0002	A	General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE	17. PRICE GROUP
A0023	Press Releases	N/A	

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE	18. ESTIMATED TOTAL PRICE
Contractor Format	C.4 Reporting	ASPR BARDA	

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases.

Frequency

- Contractor shall ensure that the KO has received and approved an advanced copy of any press release directly related to this contract not less than 5 business days prior to the issuance of the press release
- If corrective action is required, the Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases

Any final press releases shall be submitted to BARDA no later than one (1) calendar day prior to its release

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES		
	Draft	Final	
		Reg	Repro
ASPR BARDA	1	1	0
CCAP-JCRD			0
15. TOTAL →	1	1	0

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
(b) (6) (b) (6)	24 Sep 21	(b) (6) (b) (6)	24SEPT21

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved
OMB No. 0704-0188

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY:
0002	A	TDP _____ TM _____ OTHER General

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
E	W58P05-21-C-0008	GlaxoSmithKline

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
A0024	AUTHORIZATION FOR FDA TO SHARE NON-PUBLIC INFORMATION WITH THE DEPARTMENT OF DEFENSE	N/A

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
Contractor Format	C.4 Reporting	ASPR BARDA

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
N/A	C	See Blk 16	See Blk 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk 16	See Blk 16

16. REMARKS

FDA Sharing of Non-Public Information Concerning Sotrovimab with Department of Defense (DoD) Partners

Delivery of a letter to the U.S. Food and Drug Administration (FDA) authorizing FDA to exchange regulatory information with DoD for purposes related to the performance of this contract. This letter will be send (a) directly to FDA CBER [for placement in the FDA's regulatory file for Sotrovimab] with a copy to (b) the contracting officer. For more information on the details of this letter and its purpose, such information is available at: https://mrdc.amedd.army.mil/index.cfm/about/jag/pl_115-92

Frequency
This letter will be provided within 10 business days of contract signature.

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES		
	Draft	Final Reg	Final Repro
ASPR BARDA	1	1	0
CCAP JCRD			0
15. TOTAL →	1	1	0

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
(b) (6)	24 Sep 21	(b) (6)	24SEPT21

EXHIBIT B

MODEL AUTHORIZATION FOR FDA TO SHARE NON-PUBLIC INFORMATION WITH THE DEPARTMENT OF DEFENSE

[To be completed on applicant/sponsor/information-owner letterhead]

[FDA Official – e.g., Center or Office Director]

United States Food and Drug Administration

10903 New Hampshire Avenue

Building __, Room ____

Silver Spring, MD 20993

Emergency Use Authorization 100, Dated May 26, 2021

Re: FDA Sharing of Non-Public Information Concerning Sotrovimab with Department of Defense (DoD) Partners[1]

On behalf of GlaxoSmithKline LLC, I authorize the United States Food and Drug Administration (FDA) to share with DoD Partners all information concerning the above described product(s) that GlaxoSmithKline LLC has provided or will provide to FDA or to any other DoD Partner. I understand (i) that those Partners have committed to use and disclose such information only within the Government for the purposes of the DoD Partners facilitating performance under the Government contract under which this authorization is submitted, and not for the purpose of submitting regulatory filings independent of GlaxoSmithKline LLC, and (ii) that those Partners have committed and are otherwise legally required to maintain the confidentiality of, and not otherwise use, such information. I understand that the information may contain confidential commercial or financial information or trade secrets within the meaning of 18 USC § 1905, 21 USC § 331(j), and 5 USC § 552(b)(4), that is exempt from public disclosure. I agree to hold FDA harmless for any injury caused by FDA's disclosure of this information.

Authorization is given to FDA to share this information without deleting confidential commercial or financial or trade secret information. This authorization shall remain valid unless

[1] DoD Partners include the U.S. Army Medical Research and Materiel Command (USAMRMC), the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND), Joint Science and Technology Office (JSTO) of the Defense Threat Reduction Agency (DTRA), the Defense Advanced Research Projects Agency (DARPA), and other DoD entities.

revoked in writing. As indicated by my signature, I am authorized to provide this consent on behalf of GlaxoSmithKline LLC and my full name, title, address, telephone number, and facsimile number are set out below for verification.

Sincerely,

(Signature)

(Printed name)

(Title)

(Address)

(Telephone & Facsimile Numbers)

cc:

Office of Counterterrorism and Emerging Threats (OCET), Office of the Chief Scientist, FDA (EUA.OCET@fda.hhs.gov)

The primary MCM Center, as follows:
For CBER, (Counterterrorism and Medical Countermeasures Staff or CBEREUA@fda.hhs.gov)

For CDER, (Counter-Terrorism and Emergency Coordination Staff or CDEREUA@fda.hhs.gov)

For CDRH, for IVD medical devices, (device@fda.hhs.gov) and for non-IVD medical devices (cdrhemcm@fda.hhs.gov)

Security Requirements

Supply Chain Resiliency Plan

The contractor shall develop and submit within 30 calendar days of contract award, a comprehensive Supply Chain Resiliency Program that provides identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods.

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

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

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

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

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

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

Reports for critical items should include the following information:

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

The CO and COR reserve the right to request un-redacted copies of technical documents, during the period of performance, for distribution within the Government. Documents shall be provided within ten (10) days 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 30 calendar days of contract award detailed data regarding project materials, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing, processing, and fill/finish sites; and location and nature of non-clinical

and clinical studies sites. The Government may provide a table in tabular format for Contractor to be used to submit such data which would include but not be limited to the following:

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

Product Development Source Material and Manufacturing Reports and Projections

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

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

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

Contractor Locations

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

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

Access and General Protection/Security Policy and Procedures

This standard language text is applicable to ALL employees working on critical information related to Countermeasures Action Group (CAG), and to those with an area of performance within a Government controlled installation, facility or area. Employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The performer also shall provide all information required for background checks necessary to access critical information related to CAG, 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 CAG change the Government may require changes in performer security matters or processes. In addition to the industry standards for employment background checks, The Contractor must be willing to have key individuals, in exceptionally sensitive positions, identified for additional vetting by the United States Government.

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

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

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

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

Security Requirements:

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