AWARD/CONTRACT 1. THIS CONTRACT IS A RATED ORDER UNDER DPAS(15 CFR 700) RATING				RATING	PAGE OF	F PAGES 36					
2. CONTRACT ( W911QY21C001	Proc. Inst. Ident.) NO.	3. EFFECTIVE DA	<b>`</b>	,	0		4. REQU	ISITION	V/PURCHASE REQUEST/	PROJECT NO.	
5. ISSUED BY	CODE	W911QY		6 A1	DMIN	ISTERE	DBY (If othe	ar then Itom	5) CO	DE	
W6QK ACC-APG NAT				1			2 2 1 (1 <i>j</i> 0 me	57 11101 116/11	5)		
BLDG 1 GENERAL GR NATICK MA 01760-501						em 5					
				່	ee nu	em J					
		TOD the street site	annte stata e	-	ada)			8. DEL	IVE DV		
ELI L LLY AND COMP	ADDRESS OF CONTRACT	TOR (No., street, city,	, county, state a	ına zıp c	code)					OTHER (See b	elow)
1 LILLY CORPORATE	СТР								OUNTFOR PROMPTPAYME		
INDIANAPOLIS N 462											
								1	MIT INVOICES 1	ITEM	
									unless otherwise specified) ADDRESS	Sectio	on G
CODE 75602		FACILITY CODE						SHOWN			
11. SHIP TO/MA	ARK FOR CODE			12.1	PAYM	IENT W	ILL BE MA	ADE BY	COI	DE HQ0337	
							ID ACCOUNT N NTER (HQ0337		E		
				NOR	TH ENTI	TLEMENT	OPERATIONS				
	See Schedule				30X 1823 JMBUS (	317 OH 43218-2	2266				
	See Schedule										
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN				14 /		UNTING	AND APP	ROPRIA	ATION DATA		
COMPETITION:						511.0111	100110				
[ X ] 10 U.S.C. 2304(c)( 2 ) [ ] 41 U.S.C. 253(c)( )			See	e Sche	aule						
15A. ITEM NO. 15B. SUPPLIES' SERVICES		15C	QUA	NTITY	15D. UN	TI	15E. UNIT PRICE	15F. AN	IOUNT		
				-	-					+	
			_								
	SEE S	CHEDULE									
						150	G. TO TAL A		TOFCONTRACT	\$1,187,5	500,000.00
		16.	TABLE O								
(X) SEC.	DESCRIPTIO	N	PAGE(S)	(X)	SEC.				DESCRIPTION		PAGE(S)
	PART I - THE SCH			<b> </b>					CONTRACT CLAUSES		1
	TATION/ CONTRACT		1-2	X	I	-	RACT CLA				22 - 34
	LIES OR SERVICES AND		3-4 5-8	x					ENTS, EXHIBITS AND (	<u>) THER ATTAC</u>	<u>сн.</u> 35 - 36
	RIPTION/ SPECS./ WORK AGING AND MARKING	SIATEMENT	9	<u> ^</u>	J		F ATTACE		5 NTATIONS AND INSTRU	UCTIONS	33 - 30
	ECTION AND ACCEPTAL	NCE	10	<del> </del> _					RTIFICATIONS AND	JUIIONS	1
	VERIES OR PERFORMAN		11	1	K				F OFFERORS		
	RACT ADMINISTRATIO		12 - 15		L				OTICES TO OFFERORS		
X H SPEC	IAL CONTRACT REQUI	REMENTS	16 - 21		М				FOR AWARD		
CONTR	ACTING OFFICER WILL COM	PLETE ITEM 17 (SEAI	LED-BID OR	NEG	OTIATE	D PROCU	UREMENT) O	R 18 (SE	ALED-BID PROCUREMENT)	AS APPLICABL	E
	R'S NEGOTIATED AGREEMENT	Contractor is required to		18 [	] SEAL	ED-BID A	WARD (Contra	actor is not	required to sign this document )		
	copies to issuing office ) Con services set forth or otherwise identi	tractor agrees to furnish and fied above and on any conti		Your	bid on So	licitation N	umber			-	
	tion stated herein The rights and obli										
	t to and governed by the following do y, and (c) such provisions, representa								h additions or changes are set forth i ts This award consummates the con		
as are attached or incor	porated by reference herein			follow	ving docu	ments: (a) t	the Government	's solicitatio	n and your bid, and (b) this award/c	ontract No further co	
(Attachments are listed									only when awarding a sealed-bid co	utract)	
19A. NAME AN	D TITLE OF SIGNER (T	ype or print)		20A	. INAM	IE OF O	ONTRACT	INGOF	TICEK		
				TEL:					EMAIL:		
	CONTRACTOR						ATEGOE	MEDIC		200 0400	CTCNTTD.
19B. NAME OF	CONTRACTOR	ISC. DAT	E SIGNED	208.	. UNIT	ED SI'A	ATES OF A	MERICA	4	20C. DATE	SIGNED
(b) (6)		1									
BY _		10/26	120	BY_						-1	
(Signature	e of person authorized to sign		~~	(Signature of Contracting Officer)							

AWAR	D/CONTRACT	1. THIS CONTRA UNDER DPAS			ORD	ER			RATING	PAGE OF	PAGES 36
2. CONTRACT W911QY21C00	(Proc. Inst. Ident.) NO. 16	3. EFFECTIVE D			0		4. REQU	SITION	URCHASE REQUEST.	PROJECT NO.	00
5. ISSUED BY	CODE	W911QY		6. AI	DMINI	STERE	DBY (If othe	r than Item 5)	CO	DE	
W6QK ACC-APG NAT							2 21 (ij 0ine	r man nem 5)			
BLDG 1 GENERAL GI NATICK MA 01760-50				6	ee Ite	E					
INATION MA 01760-50	///			5	een	em 5					
7. NAME AND	ADDRESS OF CONTRACT	TOR (No., street, ci	ty, county, state i	and zip c	code)			8. DELIV		OTHER (See b	-1
(b) $(6)$									NTFOR PROMPTPAYME	OTHER (See by	elow)
1 LILLY CORPORATE								9. DISCOU	N I FOR PROMP I PA I ME	IN I	
	200										
								10. SUBMI	T INVOICES 1	ITEM	
									less otherwise specified)		
								TO THE A		Sectio	on G
CODE 75602	A DK FOD CODE	FACILITY CODE	(	10.1						DE HQ0337	
11. SHIP TO/M/	ARK FOR CODE						ILL BE MA			DE HQ0337	
							NTER (HQ0337	)			
					TH ENT BOX 1823		OPERATIONS				
	See Schedule					OH 43218-2	2266				
13. AUTHORIT	Y FOR USING OTHER TH	IAN FULL AND C	PEN	14. <i>A</i>	ACCOL	JNTING	GAND APP	ROPRIAT	ION DATA		
COMPETITION:			See	Sche	alub						
[X] 10 U.S.C. 2304(c)(2) [] 41 U.S.C. 253(c)()			000	, oche	uule						
15A. ITEM NO.	15B. SUF	PPLIES SERVICES	5	15C	QUA	NTITY	15D. UN	IT	15E. UNIT PRICE	15F. AM	IOUNT
	SEE S	CHEDULI	E								
	00										
						150		MOUNT			00 000 00
		16	6. TABLE (		ONTE		<b>J. IU IAL</b> A	MOUNI	OFCONTRACT	\$1,187,5	00,000.00
(X) SEC.	DESCRIPTIO		PAGE(S						DESCRIPTION		PAGE(S)
(A) BEC.	PARTI - THESCH		I AOD(5)	(A)	BLC.		РА		DESCRIPTION DNTRACT CLAUSES		TAOD(3)
X A SOLIO	CITATION/ CONTRACT		1-2	x	I	CONT	RACT CLA		JAIRACICLAUSED		22 - 34
	LIES OR SERVICES AND		3-4	-	PAI				NTS, EXHIBITS AND	OTHER ATTAC	
	RIPTION/ SPECS/ WORK		5-8	Х	J		FATTACH				35 - 36
	KAGING AND MARKING		9						ATIONS AND INSTR	UCTIONS	
	ECTION AND ACCEPTA	NCE	10		T.				<b>FIFICATIONS AND</b>		
X F DELI	VERIES OR PERFORMAN	ICE	11		K	OTHE	R STATEM	ENTSOF	OFFERORS		
X G CONT	FRACT ADMINISTRATIO	ON DATA	12 - 15		L	INSTR	S., CONDS.,	AND NO	TICES TO OFFERORS	5	
X H SPEC	IAL CONTRACT REQUI	REMENTS	16 - 21		Μ	EVALU	JATION FA	CTORS F	OR AWARD		
CONTR	ACTING OFFICER WILL COM	IPLETE ITEM 17 (SEA	LED-BID OF	R NEG	OTIATE	DPROC	UREMENT) O	R 18 (SEAL	ED-BID PROCUREMENT	AS APPLICABLE	В
	R'S NEGOTIATED AGREEMENT			18. [	] SEAL	ED-BID A	WARD (Contra	actor is not req	uired to sign this document.)		
	copies to issuing office.) Con e services set forth or otherwise identi			Your	bid on Sol	licitation N	umber			_	
sheets for the considera	ation stated herein. The rights and obli	igations of the parties to the	is								
	ct to and governed by the following do ny, and (c) such provisions, representa								ditions or changes are set forth This award consummates the co		
	rporated by reference herein.	uons, coraneadons, and s	peen readons,						nd your bid, and (b) this award/c		
(Attachments are listed				_				-	when awarding a sealed-bid co	mtract.)	
19A. NAME AN	D TITLE OF SIGNER (T	ype or print)		20A	. NAM	E OF C	ONTRACT	ING OFFIC	CER		
				(h)			/ BRA	NCH CHIEF			
				TEL:					EMAIL: (h) (6)	<u> </u>	
19B. NAME OF	CONTRACTOR	19C. DA	TE SIGNED	20B			ATES OF A	MERICA		20C. DATE	SIGNED
					(b) (6					97 Oct 00	20
BY				BY						27-Oct-20	20
	re of person authorized to sign)			51-			(Signature	of Contracting	Officer)	-1	

#### Section A - Solicitation/Contract Form

**A.1** The U.S. Army Contracting Command - Aberdeen Proving Ground (ACC-APG), Natick Division has a requirement for acquisition of the monoclonal antibody (mAb) therapeutic, LY-CoV555 (a monotherapy) in support of Joint Program Executive Office - Chemical Biological Radiological Nuclear Defense (JPEO-CBRND), the Assistant Secretary for Preparedness and Response (ASPR), and Biomedical Advanced Research and Development Authority (BARDA). All vials referenced herein are 700 milligrams.

CLIN	Ab name	Patient setting	Dose (g)	# of vials per dose (0.7g/vial)
0001	LY-CoV555	outpatient	0.7g	1

W911QY21C0016

Page 3 of 36

Section B - Supplies or Services and Prices

ITEM NO 0001	SUPPLIES/SERVICES Monoclonal Antibody LY- COST The contractor shall produc		UNIT Vial	UNIT PRICE (b) (4)	AMOUNT (b) (4) NTE
	antibody (mAb) therapeuti for a total price of (b) (4)				
	The contractor may deliver the fixed unit price per vial with the government. Any 10,000 vials.	l of <mark>(b)</mark> upon bi	lateral agreem	nent on the quantity	
	The not to exceed (NTE) p maximum quantity of 950,		represents the	fixed unit price at the	
	This is a fixed unit price co mechanism which allows f Lilly's allocation model.				
	This CLIN shall be execute CDRLs (Exhibit A) on this		, Statement of	Work (SOW) and	
	FOB: Origin (Shipping Po PROJECT: Operation War PSC CD: 6505				
				ESTIMATED COST	(b) (4)
ITEM NO 000101	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT \$0.00
	ACRN AA @ \$312,500,00 FFP	00			
	PURCHASE REQUEST N	UMBER: 001156	5573		
				NET AMT	\$0.00
	ACRN AA CIN: GFEBS00115655730	00001			\$312,500,000.00

ITEM NO 0002	SUPPLIES/SERVICES	QUANTITY 1	UNIT Job	UNIT PRICE	AMOUNT NSP
	Technical Data				
	COST				
	The contractor shall delive (CDRL) IAW deliverables FOB: Destination PROJECT: Operation War MFR PART NR: 1 PSC CD: 6505	in Section J, Exh		t Data Requirements List	
				ESTIMATED COST	\$0.00

Section C - Descriptions and Specifications

#### Statement of Work

#### C.1 EXECUTIVE SUMMARY (Scope of Project):

Manufacturing shall occur using cGMP validated manufacturing processes for bulk drug substance and fill and finished drug product. The specific objective is the acquisition of a minimum of 300,000 treatment courses (defined as 0.7g/dose/vial) for a targeted US population for delivery during the first two months after EUA or Contract Award date, whichever is later, with the possibility to acquire additional doses up to a maximum of 950,000. Any additional quantities above the minimum are dependent upon available supply to USG as determined by Lilly and need for additional product as determined by USG. The contractor shall also provide storage and distribution.

The product to be produced and delivered include the monoclonal antibody (mAb) therapeutic, LY-CoV555 (a monotherapy), subject to EUA approval.

## C.2 TASKS

Task 1: The contractor shall establish a quality agreement (CDRL A018) with the US Government on requirements for the US Government to accept packaged drug product as a completed deliverable. Quality agreement must be negotiated within the first 30 days of award and prior to Government acceptance of drug product. The drug will not transfer to US Government unless there is an active EUA for the product.

Task 2: The contractor shall provide a Product Development Source Material and Manufacturing Plan within 30 days of award to fulfill the US Government order. The manufacturing plan should include all materials required for drug substance/active pharmaceutical ingredient manufacturing and finished drug product, an acquisition plan for acquiring necessary materials, all key subcontractors and manufacturing sites, and a detailed schedule for providing the final product to the US Government.

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

Task 4: Storage. The contractor shall store the packaged drug product under cGMP conditions until the U.S. Government has directed the allocation of the product.

Task 5: Distribution. The contractor shall distribute the product as directed by the U.S. Government (USG) through the contractor's commercial distribution network with the contractor insuring against any supply loss from time of title transfer at origin through to end destination (site of administration) with replacement product transferred to the US government. Transfer of product to USG and distribution will not occur unless there is an active EUA or FDA approval/licensure for the product. Once the minimum dose requirement is met, the contractor shall communicate to USG in writing to the KO every month how many additional doses, if any, are available for acquisition along with the input data and other documentation used to run the global allocation model to allow review of how the available dose number was derived. Additional doses will only transfer to USG if Lilly has supply available and if USG determines need.

Task 6: Program Management Activities: The contractor shall establish the capacity in compliance with Food and Drug Administration (FDA) current good manufacturing practices (cGMP) regulations, and Biosafety Level standards if applicable. The contractor shall be responsible for management of all activities, including but not limited to, subcontractors to meet the goals of the contract, including holding routine meetings with USG, and completion of meeting minutes. On a monthly basis, the contractor shall provide a monthly report that includes capacity availability and utilization, as well as any issues that affect the operational availability of the reserved capacity.

The contractor shall provide minutes and reports in accordance with the following deliverables and the Contract Data Requirements List (CDRL), Section J, Exhibit A.

**Post Award Teleconference**. The contractor shall complete an initial teleconference after contract award in accordance with CDRL A001. The goal of this teleconference is to outline activities for the next 30 days and discuss agenda items for the post-award Kickoff Meeting (CDRL A002).

**Kickoff Meeting**. The Contractor shall complete a Kickoff meeting after contract award in accordance with CDRL A002. This will occur within a month of contract award, pending concurrence by the contracting officer.

**Every 2 weeks Teleconference**. The Contractor shall participate in teleconferences every 2 weeks, with BARDA to discuss the performance on the contract in accordance with CDRL A003. Meeting frequency can be increased with agreement between both parties as needed during the course of the Project.

**Quarterly Meetings**. At the discretion of the government the Contractor shall hold recurring teleconference or face-to-face Project Review Meetings up to four per year either in either Washington D.C or at work sites of the Contractor or subcontractors in accordance with CDRL A004.

**FDA Meeting Minutes and other communications with FDA**. All formal and informal communications with the FDA should be provided to BARDA in accordance with CDRL A005. Contractor shall notify BARDA of upcoming FDA meeting within 24 hours of scheduling Type A, B or C meetings OR within 24 hours of meeting occurrence for ad hoc meetings.

**Daily check in with project staff for COVID-19 Contract**. 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) in accordance with CDRL A006. Potential triggers for the check-in include but are not limited to regulatory status changes, manufacturing and or/distribution problems that will affect delivery,

**Monthly Progress Reports.** A consolidated submission of all slides and data presented at the biweekly telecons will serve as the monthly report in accordance with CDRL A007. The report only consists of a summary of quantity of product delivered, when and location of the delivery.

**Milestone Reports**. Milestone reports shall be cross-referenced to the Work Breakdown Structure (WBS), Statement of Work (SOW) and Integrated Master Schedule (IMS). As applicable, an Executive Summary highlighting the progress, issues and relevant manufacturing activities. The Executive Summary should highlight only critical issues for that reporting period and resolution approach; limited to 2 pages. This should be submitted in accordance with CDRL A008.

**Draft and Final Technical Progress Report**. A draft Final Technical Progress Report containing a summation of the work performed over the entire Contract. This report shall be in sufficient detail to fully describe the progress achieved under all milestones. Report should contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained during the Contract. Descriptions and rationale for activities and milestones that were not completed as planned should be provided. The draft report shall be duly marked as 'Draft' in accordance with CDRL A009. The final report should be submitted in accordance with CDRL A010. This report should be a comprehensive summary of the quantity of product delivered, when it was delivered and where.

**Product Development Source Material and Manufacturing Reports**. 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 in accordance with CDRL A011. The contract will provide manufacturing reports and manufacturing dose tracking projections/actuals utilizing the "COVID-19 Dose Tracking Templates" or similar.

**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 in accordance with CDRL A012.

**Pandemic Management Plan**. A pandemic facility and/or operational management plan including change procedures from normal to pandemic operations. Contractor will prepare an operational plan to continue operations in the event of a declared pandemic emergency in accordance with CDRL A013.

**Supply Chain and Distribution Tracking. Distribution Concept of Operations**. BARDA, and MCM Manufacturers play an important role in the distribution of therapeutics to the American people under a nationwide response. BARDA will work with the manufacturer to monitor what is in the manufacturing pipeline using a dose tracking templates. Contractor will relay final drug product information as it is being released to the BARDA/ASPR for allocation and ordering by state public health departments. This information will be returned to BARDA, the contractor and distributor. Distributors will use that information to ship therapeutics in bulk to sites of administration/end user. This will be done in accordance with CDRL A014.

**Distribution Plan**. This plan shall describe the Contractor's process to allocate (the global allocation model) and 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. This will be done in accordance with CDRL A015.

**Manufacturing Development Plan**. This plan shall describe describe the manufacturing process for the drug/biologic product to ensure conformity with §501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21 United States Code (USC) §351 (a)(2)(B), regarding good manufacturing practices (GMP)), but is not limited to planned or completed drug substance studies; list of excipients and information to support the safety of excipients that, when appropriate, shall be cross-referenced; drug product and formulation development summary from initial concept through final design; physicochemical and biological properties; manufacturing process development and validation program documents; container closure system documents [description, choice, rationale]; microbiological attributes documents and plans; compatibility documents (e.g., precipitation); assay development and validation, stability plan; and any associated risks.") This will be done in accordance with CDRL A016.

**Quality Management Plan**. Plan may include, but is not limited to the quality policy and objectives, management review, competencies and training, process document control, feedback, evaluation, corrective action and preventive action, process improvement, measurement, and data analysis processes. The framework is normally divided into infrastructure, senior management responsibility, resource management, lifecycle management, and quality management system evaluation. This will done in accordance with CDRL A017.

**Quality Agreement**. Agreement will determine the conditions of acceptance by the USG of the purchased product. No product will be accepted by the USG until a quality agreement is in place in accordance with CDRL A018.

**Release documentation for doses to be delivered**. In accordance with CDRL A019 contractor will deliver Certificate of Analysis and Certificate of Compliance as soon as practicable, prior to delivery.

**Manufacturing and Distribution Records**. In accordance with CDRL A020 contractor will timely deliver the following records for drug substance and drug product for USG review and comment: (1) Certificate of Analysis; (2) Certificate of Conformance/Compliance; and (3) a sample label and carton from production run.

Security Plan. In accordance with CDRL A021 the contractor will deliver a security plan within 30 days of

award.

**Supply Chain Resiliency Plan**. In accordance with CDRL A022 the contractor will deliver a supply chain resiliency plan within 30 days of award.

**Manufacturing Data Requirements**. In accordance with CDRL A023 the contractor will deliver manufacturing data requirements within 30 days of award.

**BARDA Audit**. Contractor shall accommodate periodic or ad hoc site visits 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 in accordance with CDRL A024.

**FDA Inspections**. In the event of an FDA inspection that occurs in relation to this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the COR and KO with copies of the plan for addressing areas of nonconformance 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 copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector in accordance with CDRL A025.

**QA Audits**. BARDA reserves the right to participate in QA audits performed by the Contractor. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of nonconformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action in accordance with CDRL A026.

**FDA Submissions**. The Contractor shall provide BARDA the opportunity to review and comment upon all draft submissions before submission to the FDA. Contractor shall provide BARDA with an electronic copy of the final FDA submission. All documents shall be duly marked as either "Draft" or "Final." This will be done in accordance with CDRL A027.

**EUA Filing**. The Contractor shall provide a copy of any request for EUA submitted to the FDA in accordance with CDRL A028.

**Provision of Public Law 115-92 Sponsor Authorization Letter**. The Contractor shall submit Public Law 115-92 Sponsor Authorization Letter in the Contractor's format that will be delivered to the designated OWS POC(s). This will be done in accordance with CDRL A029.

**Press Releases**. Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases in accordance with CDRL A030.

## C.3 SECURITY

The contractor shall comply with all Operation Warp Speed Security requirements in Section J Attachment 0001, OWS Security Requirements.

W911QY21C0016

Page 9 of 36

Section D - Packaging and Marking

**D.1** Marking and labeling TBD

Page 10 of 36

Section E - Inspection and Acceptance

## E.1 INSPECTION AND ACCEPTANCE

Inspection shall be at origin at the contractor's plant, conducted by the USG technical representative in accordance with the Quality Assurance (QA) plan. Acceptance shall be at origin by the ACC-APG Contracting Officer. All documentation required for both Inspection and Acceptance shall be uploaded into Wide Area Workflow (WAWF) by the contractor.

# 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

Section F - Deliveries or Performance

**F.1** Distribution. The contractor shall distribute the product as directed by the US Government through the contractor's commercial distribution network. Distribution will not occur until an EUA or FDA approval/licensure is achieved.

# DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
0001	POP 27-OCT-2020 TO 30-JUN-2021	N/A	N/A FOB: Origin (Shipping Point)	
000101	N/A	N/A	N/A	N/A
0002	POP 27-OCT-2020 TO 30-JUN-2021	N/A	BARDA <b>(b)</b> (6) BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT AUTH 200 C STREET, SW WASHINGTON DC 20024 <b>(b)</b> (6) FOB: Destination	W56XNH

## CLAUSES INCORPORATED BY REFERENCE

52.247-29 F.O.B. Origin

FEB 2006

Section G - Contract Administration Data

## G.1 GOVERNMENT CONTRACT ADMINISTRATION

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

Procuring Contracting Officer:

(b) (6)	
Contract Specialist:	
(b) (6)	

## G.2 GOVERNMENT TECHNICAL POINT OF CONTACT



## G.3 CONTRACTOR'S CONTRACT ADMINISTRATION

G.4 PLACES OF PERFORMANCE Eli Lilly and Company 1 Lilly Corporate Ctr Indianapolis, IN 46285

### G.5 NOTIFICATION OF REVISIONS AND CHANGE

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

## G.6 INVOICING INSTRUCTIONS

The contractor shall invoice for the quantity delivered at the fixed unit price. The total quantity delivered and invoiced shall not exceed the ceiling value of the CLIN(s).

The unit of measure is "vial." The negotiated firm-fixed unit price is (b) (4) The maximum quantities to be delivered are variable based on the contractor's global allocation model.

# ACCOUNTING AND APPROPRIATION DATA

COST CO	2021202220400000665 DDE: A5XAH T: \$312,500,000.00	5654255	S.0074658.5.26	6100.9000021001
ACRN	CLIN/SLIN	CIN		AMOUNT
AA	000101	GFEBS001	156557300001	\$312,500,000.00

CLAUSES INCORPORATED BY REFERENCE

252.204-7006	Billing Instructions	OCT 2005
252.232-7003	Electronic Submission of Payment Requests and Receiving	DEC 2018
	Reports	

#### 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 <u>https://www.sam.gov;</u> and

(2) Be registered to use WAWF at <u>https://wawf.eb.mil/</u> 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 <u>https://wawf.eb.mil/</u>.

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

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

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

#### COMBO

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

(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	HQ0337
Issue By DoDAAC	W911QY
Admin DoDAAC**	W911QY
Inspect By DoDAAC	S3605A/BARDA
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.

Page 15 of 36

(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.

TBD

(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 Section H - 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 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 that is both developed or obtained under performance of this contract, and identified by the Government in writing as confidential except authorized by Government personnel or upon written approval of the CO which the KO will provide in accordance with OWS or other Government policies and/or guidance. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency. The Contractor shall comply with all applicable Government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress.

Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations. No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions. The exceptions identified in this paragraph apply to all disclosures under this Section H.3 except to the extent that a disclosure is otherwise prohibited by law.

### H.2 Publication and Publicity

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

- (a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published.
- (b) Unless authorized in writing by the CO, the contractor shall not display the DoD logo including Operating Division or Staff Division logos on any publications.

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

## H.3 Confidentiality of Information

1. 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.

2. 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.

3. 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.

4. 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.

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

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

7. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

#### H.4 Regulatory Rights

This contract involves supply of a product that requires FDA pre-market approval or clearance before commercial authorization. Contractor is seeking FDA authorization or clearance for the commercialization of SARS-CoV2-MCM neutralizing monoclonal antibodies designated as LY-CoV555. The Contractor will be the Sponsor of a Regulatory Application and as such, the Contractor has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

Accordingly, the Contractor and the Government agree to the following:

- (a) DoD Medical Product Priority. PL 115-92 allows the DoD to request, and FDA to provide, assistance to expedite development of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. The contractor recognizes that only the DoD can utilize PL 115-92. As such, the contractor will work proactively with the Government to leverage this law under this contract. The contractor shall submit Public Law 115-92 Sponsor Authorization Letter to permit DoD to have Government-only access to regulatory filings that the contractor submits to the FDA for LY-CoV555 during the period of performance of this contract. This Letter will be delivered to the designated OWS POC(s) within 30 days of award.
- (b) FDA Communications and Engagement. The contractor will provide to the Government top-line summaries and key conclusions from all studies supporting the FDA regulatory filing and commercial approval to the extent that such data, summaries, and conclusions are submitted, generated, or made during the period of performance of this contract. In addition, unless the timeline for submission is insufficient to allow for Government review, the contractor will offer the Government the opportunity to review and provide comments on a final draft of regulatory submissions made during the period of performance of this contract. The Government will review any such submissions promptly upon receipt. The contractor will reasonably consider any comments provided by the Government, and prior to submission will provide notification to the Government of any additional edits or revisions. The contractor will keep the Government apprised of planned FDA meetings and post-meeting outcomes relating to activities that take place during the period of performance of this Agreement. The contractor shall provide the Government with all material communications and summaries thereof, both formal and informal, to or from FDA during

the period of performance of this contract regarding LY-CoV555 as soon as possible but not later than within 48 hours. The contractor shall notify the FDA that the Government has the right to discuss with FDA any development efforts regarding this product consistent with the terms of this contract.

#### H.5 Regulatory Compliance

1. The manufacturing described in the Statement of Work will comply with Current Good Manufacturing Practices (cGMP) regulations at 21 CFR 210 and 211 subject to any guidance, exemptions, or waivers issued by the FDA. Production shall occur using cGMP validated manufacturing process, fully compliant with 21 CFR 210 and 211, for bulk drug substance and fill and finished drug product subject to any guidance, exemptions, or waivers issued by the FDA.

2. 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"):

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

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

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

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

The Government may not use, or authorize the use of, any products or materials provided under this contract, unless such use occurs in the United States (or a U.S. territory where U.S. law applies such as embassies, military and NATO installations) and protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act Declaration of equal or greater scope. Any use where the application of the PREP Act is in question will be discussed with Lilly prior to use and, if the parties disagree on such use, the dispute will be resolved according to the "Disputes Clause" (52.233-1).

The items and technology covered by this Contract are being developed for both civil and military applications.

### H.7 Sales to Covered Nations

(i) Due to the exceptional and unprecedented nature of the COVID-19 threat to global public health, as well as the investments made towards the development of a safe and effective therapeutic against COVID-19, Lilly agrees that it will not at any time prior to 30 June 2021 sell any COVID-19 therapeutic supplied directly to the Government under this Agreement to any centralized federal authority (i.e., federal government or equivalent) of a nation that is a

member of the Group of Seven plus Switzerland ("Covered Nation") at a lower price than the prices set forth in this contract.

(ii) If, at any time prior to 30 June 2021, Lilly enters into any agreement with a Covered Nation to sell the COVID-19 therapeutic supplied to the Government under this Agreement at a price lower than the price currently paid by the U.S. Government for the same COVID-19 therapeutic doses under this contract, Lilly shall provide notice within 30 days to the U.S. Government and the U.S. Government may elect, at its discretion, to receive the benefit of this provision and receive such COVID-19 therapeutic doses at that lower price.

(iii) Upon any such election by the U.S. Government, this contract shall be deemed to have been amended and modified such that, from the date on which the more favorable pricing was first provided to any Covered Nation (the "Amended Pricing Effective Date"), the U.S. Government will receive that lower price for all orders of COVID-19 therapeutic doses following that Amended Pricing Effective Date.

(iv) Any price reductions provided hereunder are not intended as an inducement or reward for any procurement or purchasing decisions by the U.S. Government of any Lilly product.

#### H.8 Ensuring Sufficient Supply of the Product

1. In recognition of the Government's need to provide sufficient quantities of a COVID-19 therapeutic to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions ((a) and (b)) are met:

- (a) Lilly 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 to delivery of the minimum required doses to USG under this contract, well as all additional orders accepted by Contractor, 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 therapeutic to the Government prior to delivery of the minimum required doses to USG under this contract, as well as all additional orders accepted by Contractor, other than as a result of clinical failure, or serious technical or safety reasons; or any filing that anticipates Federal bankruptcy protection; and
- (b) Lilly has submitted an Emergency Use Authorization application under §564 of the FD&C Act or a biologics license application provisions of §351(a) of the Public Health Service Act (PHSA).

2. If both conditions listed in section 1 occur, Lilly, 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 for exclusive sale to the U.S. Government:

- (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 Lilly Background Patent, Copyright, other Lilly Intellectual Property, Lilly Know-How, Lilly Technical Data rights necessary to manufacture doses of the SARS-CoV2-MCM neutralizing monoclonal antibodies designated as LY-CoV555 and the combination therapy LY-CoV555 and LY-CoV016 therapeutic; b. necessary FDA regulatory filings or authorizations owned or controlled by Lilly related to this product therapeutic and any confirmatory instrument pertaining thereto; and
- (b) 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 Contractor.

#### H.9 Transportation to Final Destination

During the course of performance under this contract, the Government may require storage of the drug product before delivery to the final government location. In these circumstances, the Government will accept the drug product 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 for up to sixty (60) calendar days after acceptance. Regardless of where acceptance occurs, risk of loss of or damage to supplies shall remain with the contractor until delivery of final product to a government facility or a third-party delivery location identified by the Government.

#### H.10 Validation of IP/Data

The Parties acknowledge that the following background intellectual property and technical data assertions have been made:

List of Lilly Patent Applications Related to LY-CoV555 (bamlinvimab) Asserted October 19, 2020

1. Patent Family Titled: "Anti-Coronavirus Antibodies and Methods of Use"

• (b) (4)

2. Patent Family Titled: "Methods for Reducing Host Cell Protein Content in Protein Purification Processes"

• (b) (4)

The parties agree that, should additional information relevant to these assertions become available, the parties will reevaluate said assertions as necessary in the future.

### H.11 Combination Therapy Negotiation

It is the intention of the parties that Lilly and the government enter into this contract for the monoclonal antibody therapeutic, while awaiting EUA on the combination therapy LY-CoV016. In the event that the combination therapy receives EUA, the parties agree to negotiate in good faith a separate contract for the combination therapy.

### H.12 Buy Back

It is the intention of the parties that Lilly does not want to sell, nor does the Government want to purchase, therapeutics that are not FDA-authorized or approved or for which an EUA has been revoked. In the event that the EUA for the monoclonal antibody therapeutic is revoked, Lilly agrees to buy back from the Government all treatments (as defined in the CLIN) accepted by the Government. Lilly shall notify the contracting officer immediately upon notification of revocation. Lilly shall repurchase the treatments within (30) days of the EUA revocation at the same price as purchased by the Government unless otherwise agreed.

#### H.13 Modification to Contract

This contract contemplates acquisition of the monoclonal antibody therapeutic LY-CoV555 as long as there is approval and utility of this product. In the event of unforeseen circumstances including, but not limited to, delays in manufacturing, unforeseen U.S. regulatory actions, or revocation of EUA, the parties agree to negotiate in good faith, a modification to the contract to revise the minimum and/or maximum quantities and/or the period of performance.

Page 22 of 36

#### Section I - Contract Clauses

## CLAUSES INCORPORATED BY REFERENCE

52 202 1		U.D.L 2020
52.202-1	Definitions	JUN 2020
52.203-3	Gratuities	APR 1984
52.203-12	Limitation On Payments To Influence Certain Federal	JUN 2020
50.004.4	Transactions	1411 0011
52.204-4	Printed or Copied Double-Sided on Postconsumer Fiber	MAY 2011
52 204 12	Content Paper	OCT 2019
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
52.212-4	Contract Terms and ConditionsCommercial Items	OCT 2018
52.215-8	Order of PrecedenceUniform Contract Format	OCT 1997
52.219-9 (Dev)	Small Business Subcontracting Plan (Deviation 2018-00018)	JUN 2020
52.222-3	Convict Labor	JUN 2003
52.222-19	Child Labor Cooperation with Authorities and Remedies	JAN 2020
52.222-36	Equal Opportunity for Workers with Disabilities	JUN 2020
52.222-40	Notification of Employee Rights Under the National Labor	DEC 2010
	Relations Act	
52.222-50	Combating Trafficking in Persons	JAN 2019
52.223-18	Encouraging Contractor Policies To Ban Text Messaging	JUN 2020
	While Driving	
52.225-13	Restrictions on Certain Foreign Purchases	JUN 2008
52.227-1	Authorization and Consent	JUN 2020
52.227-2	Notice And Assistance Regarding Patent And Copyright	JUN 2020
	Infringement	
52.227-3	Patent Indemnity	APR 1984
52.229-3	Federal, State And Local Taxes	FEB 2013
52.232-17	Interest	MAY 2014
52.232-22	Limitation Of Funds	APR 1984
52.232-23	Assignment Of Claims	MAY 2014
52.232-33	Payment by Electronic Funds TransferSystem for Award	OCT 2018
	Management	
52.232-39	Unenforceability of Unauthorized Obligations	JUN 2013
52.232-40	Providing Accelerated Payments to Small Business	DEC 2013
	Subcontractors	
52.233-1	Disputes	MAY 2014
52.242-5	Payments to Small Business Subcontractors	JAN 2017
52.242-13	Bankruptcy	JUL 1995
52.244-5	Competition In Subcontracting	DEC 1996
252.203-7001	Prohibition On Persons Convicted of Fraud or Other Defense-	
	Contract-Related Felonies	
252.203-7002	Requirement to Inform Employees of Whistleblower Rights	SEP 2013
252.203-7003	Agency Office of the Inspector General	AUG 2019
252.204-7002	Payment For Contract Line or Subline Items Not Separately	APR 2020
	Priced	
252.204-7006	Billing Instructions	OCT 2005
252.225-7048	Export-Controlled Items	JUN 2013
252.227-7015	Technical DataCommercial Items	FEB 2014
252.244-7000	Subcontracts for Commercial Items	JUN 2013

Page 23 of 36

#### CLAUSES INCORPORATED BY FULL TEXT

# 52.204-24 REPRESENTATION REGARDING CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUG 2020)

The Offeror shall not complete the representation at paragraph (d)(1) of this provision if the Offeror has represented that it "does not provide covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, or other contractual instrument" in the provision at 52.204-26, Covered Telecommunications Equipment or Services-Representation, or in paragraph (v) of the provision at 52.212-3, Offeror Representations and Certifications-Commercial Items.

(a) Definitions. As used in this provision-

Backhaul, covered telecommunications equipment or services, critical technology, interconnection arrangements, reasonable inquiry, roaming, and substantial or essential component have the meanings provided in the clause 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

(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. Nothing in the prohibition shall be construed to--

(i) Prohibit the head of an executive agency from procuring with an entity to provide a service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

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

(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. 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. Nothing in the prohibition shall be construed to--

(i) Prohibit the head of an executive agency from procuring with an entity to provide a service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

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

(c) Procedures. The Offeror shall review the list of excluded parties in the System for Award Management (SAM) (https://www.sam.gov) for entities excluded from receiving federal awards for "covered telecommunications equipment or services."

(d) Representations. The Offeror represents that--

(1) It [] will, [] will not provide covered telecommunications equipment or services to the Government in the performance of any contract, subcontract or other contractual instrument resulting from this solicitation. The Offeror shall provide the additional disclosure information required at paragraph (e)(1) of this section if the Offeror responds "will" in paragraph (d)(1) of this section; and

(2) After conducting a reasonable inquiry, for purposes of this representation, the Offeror represents that--

It [] does, [] does not use covered telecommunications equipment or services, or use any equipment, system, or service that uses covered telecommunications equipment or services. The Offeror shall provide the additional disclosure information required at paragraph (e)(2) of this section if the Offeror responds "does" in paragraph (d)(2) of this section.

(e) Disclosures.

(1) Disclosure for the representation in paragraph (d)(1) of this provision. If the Offeror has responded "will" in the representation in paragraph (d)(1) of this provision, the Offeror shall provide the following information as part of the offer:

(i) For covered equipment--

(A) The entity that produced the covered telecommunications equipment (include entity name, unique entity identifier, CAGE code, and whether the entity was the original equipment manufacturer (OEM) or a distributor, if known);

(B) A description of all covered telecommunications equipment offered (include brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); and

(C) Explanation of the proposed use of covered telecommunications equipment and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(1) of this provision.

(ii) For covered services--

(A) If the service is related to item maintenance: A description of all covered telecommunications services offered (include on the item being maintained: Brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); or

(B) If not associated with maintenance, the Product Service Code (PSC) of the service being provided; and explanation of the proposed use of covered telecommunications services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(1) of this provision.

(2) Disclosure for the representation in paragraph (d)(2) of this provision. If the Offeror has responded "does" in the representation in paragraph (d)(2) of this provision, the Offeror shall provide the following information as part of the offer:

(i) For covered equipment--

(A) The entity that produced the covered telecommunications equipment (include entity name, unique entity identifier, CAGE code, and whether the entity was the OEM or a distributor, if known);

(B) A description of all covered telecommunications equipment offered (include brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); and

(C) Explanation of the proposed use of covered telecommunications equipment and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(2) of this provision.

(ii) For covered services--

(A) If the service is related to item maintenance: A description of all covered telecommunications services offered (include on the item being maintained: Brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); or

(B) If not associated with maintenance, the PSC of the service being provided; and explanation of the proposed use of covered telecommunications services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(2) of this provision.

(End of provision)

# 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, or as critical technology as part of any system, or as critical technology as part of any system, or as critical technology as part of any system, or as critical technology as part of any system, or as critical technology as part of any system, or as critical technology as part 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 <a href="https://dibnet.dod.mil">https://dibnet.dod.mil</a>. For indefinite delivery contracts, the Contractor shall report to the Contractor of the Department of Defense, identify both the indefinite delivery contract and 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 <a href="https://dibnet.dod.mil">https://dibnet.dod.mil</a>.

(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)

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

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

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

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

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

Page 28 of 36

(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.)

X (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).

X (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.)

**X** (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).

**X** (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).

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

\_\_\_\_\_(10) [Reserved]

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

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

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

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

\_\_\_\_ (13) [Reserved]

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

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

#### Page 29 of 36

- (15)(i) 52.219-7, Notice of Partial Small Business Set-Aside (MAR 2020) (15 U.S.C. 644).
- (ii) Alternate I (MAR 2020) of 52.219-7.
- (16) 52.219-8, Utilization of Small Business Concerns (OCT 2018) (15 U.S.C. 637(d)(2) and (3)).
- X (17)(i) 52.219-9, Small Business Subcontracting Plan (JUN 2020) (15 U.S.C. 637(d)(4)).
- (ii) Alternate I (NOV 2016) of 52.219-9.
- (iii) Alternate II (NOV 2016) of 52.219-9.
- (iv) Alternate III (JUN 2020) of 52.219-9.
- \_\_\_\_ (v) Alternate IV (JUN 2020) of 52.219-9.
- (18) (i) 52.219-13, Notice of Set-Aside of Orders (MAR 2020) (15 U.S.C. 644(r)).
- (ii) Alternate I (MAR 2020) of 52.219-13.
- (19) 52.219-14, Limitations on Subcontracting (MAR 2020) (15 U.S.C. 637(a)(14)).
- (20) 52.219-16, Liquidated Damages—Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).
- (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (MAR 2020) (15 U.S.C. 657f).
- X (22) (i) 52.219-28, Post Award Small Business Program Rerepresentation (MAY 2020) (15 U.S.C. 632(a)(2)).

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

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

(24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (MAR 2020) (15 U.S.C. 637(m)).
 (25) 52.219-32, Orders Issued Directly Under Small Business Reserves (MAR 2020) (15 U.S.C. 644(r)).

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

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

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

- X (29) 52.222-21, Prohibition of Segregated Facilities (APR 2015).
- \_\_\_\_\_ (30)(i) 52.222-26, Equal Opportunity (SEPT 2016) (E.O. 11246).
- (ii) Alternate I (FEB 1999) of 52.222-26.
- (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.
- \_\_\_\_\_(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.

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

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

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

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

**X** (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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

\_\_\_\_\_ (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)).

**X** (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).

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

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

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

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

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

Page 32 of 36

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(B) Alternate I (March 2, 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627). (xiv) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (May 2014) (41 U.S.C. chapter 67.)

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

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

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

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

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

(B) Alternate I (Jan 2017) of <u>52.224-3</u>.

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

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

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

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

(End of clause)

## 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

https://www.acquisition.gov/content/regulations

(End of clause)

#### 52.252-6 AUTHORIZED DEVIATIONS IN CLAUSES (APR 1984)

(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)

Page 35 of 36

#### Section J - List of Documents, Exhibits and Other Attachments

Document Type	Description	Page #	Date
Exhibit A	CDRLs	32	26 October 2020
Attachment 0001	Security Requirements	6	11 October 2020

Data Item #	Title of Data Item	Date
A001	Post Award Teleconference Minutes	26 October 2020
A002	Kickoff Meeting Agenda and Minutes	26 October 2020
A003	Teleconference Minutes	26 October 2020
A004	Quarterly Meeting Minute	26 October 2020
A005	FDA Meeting Minutes	26 October 2020
A006	Daily Check-in Updates	26 October 2020
A007	Monthly/Annual Tech Progress Reports/Annual Meeting	26 October 2020
A008	Milestone Reports	26 October 2020
A009	Draft Technical Progress Report	26 October 2020
A010	Final Technical Progress Report	26 October 2020
A011	Product Development Source Material and Manufacturing Reports	26 October 2020
A012	Contractor Locations	26 October 2020
A013	Pandemic Management Plan	26 October 2020
A014	Supply Chain and Distribution Tracking	26 October 2020
A015	Distribution Plan	26 October 2020
A016	Manufacturing Development Plan	26 October 2020
A017	Quality Management Plan	26 October 2020
A018	Quality Agreement	26 October 2020
A019	Release Documentation for Doses to be Delivered	26 October 2020
A020	Manufacturing and Distribution Records	26 October 2020
A021	Security Plan	26 October 2020
A022	Supply Chain Resiliency Plan	26 October 2020
A023	Manufacturing Data Requirements	26 October 2020
A024	BARDA Audit Report	26 October 2020
A025	FDA Inspections	26 October 2020
A026	QA Audit Reports	26 October 2020
A027	FDA Submissions	26 October 2020
A028	EUA Filing	26 October 2020
A029	Provision of Public Law 115-92 Sponsor Authorization Letter	26 October 2020
A030	Press Releases	26 October 2020

Exhibit A Contract Data Requirements List (CDRL)

# W911QY21C0016

Page 36 of 36

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1 CONTRACT ID CODE		PAGE OF PAGES
AMENDMENT OF SOLICITA		ICATION OF CONTRACT		S		1 6
2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO			5 PROJECT	NO (Ifapplicable)
P00001	09-Nov-2020	SEE SCHEDULE				
6 ISSUED BY CODE	W911QY	7 ADMINISTERED BY (Ifother than item 6)		COD	E	
W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	norman	See Item 6				
NAME AND ADDRESS OF CONTRACTOR	No. Street County	tate and Zin Code)	9A AN	MENDME	NT OF SO	LICIT AT ION NO.
8. NAME AND ADDRESS OF CONTRACTOR ( ELLLLY AND COMPANY	No., Street, County, 2	state and Zip Code)	JA. A		111 01 50	LICITATION NO.
1L LLY CORPORATE CTR INDIANAPOLIS IN 46285			9B. DA	ATED (SE	E ITEM 11	)
						T/ORDER NO.
	I				SEE ITEM	13)
CODE 75602	FACILITY COD		X 27-Oct			
		PPLIES TO AMENDMENTS OF SOLI			7.	
The above numbered solicitation is amended as set forth			is extend		is not exter	ıded
Offer must acknowledge receipt of this amendment prior	•				e enhenitted.	
(a) By completing Items 8 and 15, and returning or (c) By separate letter or telegram which includes a re-		it; (b) By acknowledging receipt of this amendme and amendment numbers FAILURE OF YOUR A	-	-		
RECEIVED AT THE PLACE DESIGNATED FOR TH						
REJECTION OF YOUR OFFER If by virtue of this am provided each telegram or letter makes reference to the s				-	er,	
12. ACCOUNTING AND APPROPRIATION DA	TA (If required)					
See Schedule						
		O MODIFICATIONS OF CONTRACT				
A. THIS CHANGE ORDER IS ISSUED PURSU CONTRACT ORDER NO. IN ITEM 10A.	ANT TO: (Specify a	uthority) THE CHANGES SET FORTH	IN ITEM 1	4 ARE M	ADE IN TI	ΗE
X B. THE ABOVE NUMBERED CONTRACT/O office, appropriation date, etc.) SET FORT					s changes ir	n paying
C. THIS SUPPLEMENTAL AGREEMENT IS	ENTERED INTO PU	RSUANT TO AUTHORITY OF:				
D. OTHER (Specify type of modification and a	authority)					
E. IMPORTANT: Contractor X is not,	is required to sig	n this document and return	copies to th	he issuing	office.	
14. DESCRIPTION OF AMENDMENT/MODIFI where feasible.) Modification Control Number: jpapa21420 MODIFICATION OBLIGATION AMOUNT: \$62,50	)	by UCF section headings, including solic	itation/cont	tract subje	ct matter	
1. The purpose of this modification is to add in Specialist information in Section G.1, change t DoDAAC from HQ0337 to HQ0490 in WAWF of	he payment office Do	DAAC from HQ0337 to HQ0490, and t				act
2. These changes were requested by the requiring activity in order to meet mission goals.						
3. As a result of this modification, the total func \$375,000,000.00. The total value and all other			00.00 from \$	\$312,500	,000.00 to	
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect						
15A. NAME AND TITLE OF SIGNER (Type or	print)	16A. NAME AND TITLE OF CO	FFICER	NG OFFIC	ER (Type o	or print)
15B. CONTRACT OR/OFFEROR	15C. DATE SIGNEI			لاوبنديد	160	C. DATE SIGNED
		(b) (6) BY				9-Nov-2020
(Signature of person authorized to sign)		(Signature of Contracting Of	ficer)			
EXCEPTION TO SF 30	3	30-105-04		STA	NDARD FO	ORM 30 (Rev. 10-83)

# **SUMMARY OF CHANGES**

# SECTION A - SOLICITATION/CONTRACT FORM

The 'Payment will be made by' organization has changed from
DEFENSE FINANCE AND ACCOUNTING SERVICE
DFAS - COLUMBUS CENTER (HQ0337)
NORTH ENTITLEMENT OPERATIONS
P.O. BOX 182317
COLUMBUS OH 43218-2266
to
DEFENSE FINANCE AND ACCOUNTING SERVICE
DFAS-INDY VP GFEBS
8899 E 56TH STREET
INDIANAPOLIS IN 46249-3800

# SECTION B - SUPPLIES OR SERVICES AND PRICES

SUBCLIN 000102 is added as follows:

ITEM NO 000102	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT \$0.00
	ACRN AA @ \$62,500,00	0.00			
	FFP				
	PR #0011565573-0001				
	PURCHASE REQUEST N	NUMBER: 001156	5573-0001		

	NET AMT	\$0.00
ACRN AA CIN: GFEBS001156557300002		\$62,500,000.00

# SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Sch	edule was added fo	or SUBCLIN 000102:	
INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

# SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by \$62,500,000.00 from \$312,500,000.00 to \$375,000,000.00.

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

ACRN: AA

CIN: GFEBS001156557300002

Acctng Data: 0212021202220400000665654255

S.0074658.5.26 61

6100.9000021001

Increase: \$62,500,000.00

Total: \$62,500,000.00

Cost Code: A5XAH

The following have been modified:

# G.1 GOVERNMENT CONTRACT ADMINISTRATION

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

Procuring Contracting Officer:

(b) (6)

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

Contract Specialist:

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

# G.2 GOVERNMENT TECHNICAL POINT OF CONTACT

(b) (6) Project Officer 200 C Street, SW Washington, DC 20024

# G.3 CONTRACTOR'S CONTRACT ADMINISTRATION

(b) (6) Eli Lilly and Company 1 Lilly Corporate Ctr Indianapolis, IN 46285

# G.4 PLACES OF PERFORMANCE Eli Lilly and Company 1 Lilly Corporate Ctr Indianapolis, IN 46285

# G.5 NOTIFICATION OF REVISIONS AND CHANGE

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

# G.6 INVOICING INSTRUCTIONS

The contractor shall invoice for the quantity delivered at the fixed unit price. The total quantity delivered and invoiced shall not exceed the ceiling value of the CLIN(s).

The unit of measure is "vial." The negotiated firm-fixed unit price is (b) . The maximum quantities to be delivered are variable based on the contractor's global allocation model.

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 <u>https://www.sam.gov;</u> and

(2) Be registered to use WAWF at <u>https://wawf.eb mil/</u> 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 <u>https://wawf.eb.mil/</u>.

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

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

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

COMBO

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

(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.

# Field Name in WAWFData to be entered in WAWFPay Official DoDAACHQ0490Issue By DoDAACW911QYAdmin DoDAAC\*\*W911QYInspect By DoDAACS3605A/BARDAShip To Code7BM13 – Amerisource Bergen Corporation

# Routing Data Table\*

(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.

TBD

(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

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1 CONTRACT	1 CONTRACT ID CODE	
AMENDMENT OF SOLICITA	ATION/MODIF	ICATION OF CONTRACT	S		1 4
2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO		5 PROJECT	NO (Ifapplicable)
P00002	18-Nov-2020	SEE SCHEDULE			
6 ISSUED BY CODE	W911QY	7 ADMINISTERED BY (Ifother than item 6)	CO	DE	
WEQK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011		See Item 6			
8. NAME AND ADDRESS OF CONTRACTOR	No Street County S	State and Zip Code)	9A. AMENDM	ENT OF SOI	LICITATION NO.
ELILLY AND COMPANY	(110., Sileer, coulty, t		9B. DATED (S	EE ITEM 11	)
INDIANAPOLIS IN 46285			X 10A MOD OF W911QY21C0	CONTRACT	Γ/ORDER NO.
			10B. DATED		
CODE 75602	FACILIT Y COD	DE	X 27-Oct-2020	-	
11.	THIS ITEM ONLY A	PPLIES TO AMENDMENTS OF SOLI	CITATIONS		
The above numbered solicitation is amended as set forth	n in Item 14 The hour and	date specified for receipt of Offer	is extended,	is not exten	ıded
Offer must acknowledge receipt of this amendment prio	r to the hour and date spec	ified in the solicitation or as amended by one oft	he following methods:	_	
(a) By completing Items 8 and 15, and returning		t; (b) By acknowledging receipt of this amendme	• •		
or (c) By separate letter or telegram which includes a re RECEIVED AT THE PLACE DESIGNATED FOR TH				TO BE	
REJECTION OF YOUR OFFER If by virtue of this an	mendment you desire to cha	nge an offer already submitted, such change may b	oe made by telegram or le	tter,	
provided each telegramor letter makes reference to the	solicitation and this amend	lment, and is received prior to the opening hour a	nd date specified		
12. ACCOUNTING AND APPROPRIATION DA	ATA (If required)				
		O MODIFICATIONS OF CONTRACTS CT/ORDER NO. AS DESCRIBED IN ITI			
A. THIS CHANGE ORDER IS ISSUED PURSU CONTRACT ORDER NO. IN ITEM 10A.	JANT TO: (Specify a	uthority) THE CHANGES SET FORTH	IN ITEM 14 ARE N	ADE IN TH	Æ
X B. THE ABOVE NUMBERED CONTRACT/C office, appropriation date, etc.) SET FORT				as changes in	ı paying
C. THIS SUPPLEMENTAL AGREEMENT IS	ENTERED INTO PU	URSUANT TO AUTHORITY OF:			
D. OTHER (Specify type of modification and	authority)				
E. IMPORTANT: Contractor X is not,	is required to sig	n this document and return	copies to the issuin	g office.	
14. DESCRIPTION OF AMENDMENT/MODIFI where feasible.) Modification Control Number: (0)(6) 21514 MODIFICATION OBLIGATION AMOUNT: \$0.00		by UCF section headings, including solic	itation/contract subj	ect matter	
1. The purpose of this modification is to chang	e/correct the <b>I</b> nspect	By DoDAAC from S3605A/BARDA to	W911QY/BARDA in	WAWF clau	ıse 252.232-7006.
2. This change is necessary to allow the cont	ractor to invoice prop	erly in WAWF.			
3. The total contract value and all other terms	and conditions remair	n unchanged.			
Except as provided herein, all terms and conditions of the do	ocument referenced in Item	9A or 10A, as heretofore changed, remains uncha	nged and in full force and	effect	
15A. NAME AND TITLE OF SIGNER (Type or		16A. NAME AND TITLE OF CO	NTRACTING OFFI	CER (Type o	or print)
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNEI	D 16B_UNITED STATES OF AME	EMAL: (b) (6) RICA		C. DATE SIGNED
		(b) (6) BY		~	3-Nov-2020
(Signature of person authorized to sign)		(Signature of Contracting Of	ficer)		_
EXCEPTION TO SF 30	3	30-105-04	STA	ANDARD FO	ORM 30 (Rev. 10-83)

# SUMMARY OF CHANGES

# SECTION G - CONTRACT ADMINISTRATION DATA

The following have been modified:

# 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 <u>https://www.sam.gov;</u> and

(2) Be registered to use WAWF at <u>https://wawf.eb mil/</u> 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 <u>https://wawf.eb.mil/</u>.

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

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

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

## COMBO

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

(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	W911QY
Admin DoDAAC**	W911QY
Inspect By DoDAAC	W911QY/BARDA
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.

TBD

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

(End of clause)

W911QY21C0016 P00002 Page 4 of 4

A MENDMENT OF SOLICITA	TIONMODIE	ICATION OF CONTRACT	. 1	CONTRACT	D CODE	PAGE OF PAGES
AMENDMENT OF SOLICITA	TION/MODIF	ICATION OF CONTRACT		S		1 3
2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO			5 PROJECTI	NO (Ifapplicable)
P00003	19-Nov-2020	SEE SCHEDULE				
6 ISSUED BY CODE	W911QY	7 ADMINISTERED BY (Ifother than item 6)		COL	DE	
W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011		See Item 6				
8. NAME AND ADDRESS OF CONTRACTOR (	No., Street, County, S	State and Zip Code)	9A	AMENDM	ENT OF SOI	LICITATION NO.
ELI L LLY AND COMPANY			9B.	DATED (SE	EE ITEM 11	)
			X 104	A. MOD. OF 011QY21C00	CONTRACT	Γ/ORDER NO.
				B. DATED (	SEE ITEM 1	13)
CODE 75602	FACILITY COE	DE PPLIES TO AMENDMENTS OF SOLI		-Oct-2020		
The above numbered solicitation is amended as set forth				tended.	is not exten	ded
					IS HOT EXTEN	ueu
Offer must acknowledge receipt of this amendment prio (a) By completing Items 8 and 15, and returning		ined in the solicitation of as amended by one of this amendments (b) By acknowledging receipt of this amendments		-	er submitted ·	
or (c) By separate letter or telegram which includes a re	_ •				-	
RECEIVED AT THE PLACE DESIGNATED FOR TH						
REJECTION OF YOUR OFFER If by virtue of this and provided each telegram or letter makes reference to the s			-	-	ter,	
12. ACCOUNT ING AND APPROPRIATION DA						
13 THISITE	M APPLIES ONLY T	O MODIFICATIONS OF CONTRACT	S/ORDE	RS		
		CT/ORDER NO. AS DESCRIBED IN IT		NO.		
A. THIS CHANGE ORDER IS ISSUED PURSU CONTRACT ORDER NO. IN ITEM 10A.	IANT TO: (Specify a	uthority) THE CHANGES SET FORTH	IN ITE	M 14 ARE M	IADE IN TH	Æ
B. THE ABOVE NUMBERED CONTRACT/O office, appropriation date, etc.) SET FORT					as changes in	a paying
X C. THIS SUPPLEMENTAL AGREEMENT IS 45 CFR part 101, Health Resources and Prior	ENTERED INTO PU	RSUANT TO AUTHORITY OF:				
D. OTHER (Specify type of modification and						
E. IMPORTANT: Contractor is not,	χ is required to sig	n this document and return 1	conies	to the issuing	office	
	<u></u>	<u> </u>	-		-	
where feasible.) Modification Control Number: (1)(6)21546		by OCF section neadings, including sone	211411011/0	contract subje	ect matter	
OBLIGATION AMOUNT: \$0.00						
See Block 14 continuation page.						
			_			
Except as provided herein, all terms and conditions of the do		-	-			
15A. NAME AND TITLE OF SIGNER (Type or	pimi)	16A. NAME AND TITLE OF CO				n primi)
	440 E ·			<sup>IAL:</sup> (b) (6)		
15B_CONTRACTOR/OFFEROR	15C. DATE SIGNEI	D 16B. UNITED STATES OF AME BY (b) (6)	RICA		× 1	C. DATE SIGNED
(Signature of person authorized to sign)		(Signature of Contracting Of	fficer)		20	-1404-2020
EXCEPTION TO SF 30 APPROVED BY OIRM 11-84	-	30-105-04			NDARD FO	ORM 30 (Rev. 10-83)

# SUMMARY OF CHANGES

# SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

The purpose of this modification is to:

1. Add a Health Resources Priorities and Allocations System (HRPAS) priority rating of DO-HR to this contract:

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

2. Add a Defense Priorites and Allocation System (DPAS) priority rating of DO-C9 to this contract to act as the equivalent to the HRPAS priority rating of DO-HR.

3. Add FAR 52.211-15, Defense Priority and Allocation Requirements

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

The total funded amount and total contract price remain unchanged.

# SECTION A - SOLICITATION/CONTRACT FORM The DPAS code DO-C9 has been added.

SECTION I - CONTRACT CLAUSES

The following have been added by full text:

52.211-15 DEFENSE PRIORITY AND ALLOCATION REQUIREMENTS (APR 2008)

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

(End of clause)

# SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

Document Type	Description	Page #	Date
Exhibit A	CDRLs	32	26 October 2020
Attachment 0001	Security Requirements	6	11 October 2020

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRAC				1. CONTRACT ID CODE		PAGE OF PAGES
AMENDMENT OF SOLICITA		ICATION OF CONTRACT		S		1 3
2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.			5. PROJECT N	IO.(Ifapplicable)
P00004	25-Nov-2020	SEE SCHEDULE				
6. ISSUED BY CODE	W911QY	7. ADMINISTERED BY (If other than item 6)		COI	DE	
W6QK ACC-APG NATICK DIVISION		Cas have 0				
BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011		See Item 6				
8. NAME AND ADDRESS OF CONTRACTOR ( ELI ULLY AND COMPANY	No., Street, County, S	state and Zip Code)	94	A. AMENDMI	ENT OF SOL	ICITATION NO.
1 ULLY CORPORATE CTR			9F	B. DATED (S	EE ITEM 11	)
INDIANAPOLIS IN 46285						
			X 10	A. MOD. OF 911QY21C0	CONTRACI	VORDER NO.
				B. DATED (		
CODE 75602	FACILIT Y COD	E		7-Oct-2020		- /
11.7		PPLIES TO AMENDMENTS OF SOLI	CITAT	IONS		
The above numbered solicitation is amended as set forth	in Item 14. The hour and o	date specified for receipt of Offer	is e	extended,	is not exten	led.
Offer must acknowledge receipt of this amendment prior	r to the hour and date speci	ified in the solicitation or as amended by one of t	he follov	ving methods:		
(a) By completing Items 8 and 15, and returning		t; (b) By acknowledging receipt of this amendme				
or (c) By separate letter or telegram which includes a re RECEIVED AT THE PLACE DESIGNATED FOR TH					IO BE	
REJECTION OF YOUR OFFER. If by virtue of this and					ter,	
provided each telegramor letter makes reference to the s		ment, and is received prior to the opening hour a	and date s	specified.		
12. ACCOUNTING AND APPROPRIATION DA	TA (If required)					
See Schedule			CODDI	700		
		O MODIFICATIONS OF CONTRACT T/ORDER NO. AS DESCRIBED IN ITI				
A. THIS CHANGE ORDER IS ISSUED PURSU					ADE IN TH	E
CONTRACT ORDER NO. IN ITEM 10A.						
B. THE ABOVE NUMBERED CONTRACT/O	RDFR IS MODIFIED	TO REFLECT THE ADMINISTRATION	VE CH	NGES (such	as changes in	naving
office, appropriation date, etc.) SET FORT					as changes m	paying
C. THIS SUPPLEMENTAL AGREEMENT IS	ENTERED INTO PU	RSUANT TO AUTHORITY OF:				
<b>X</b> D. OTHER (Specify type of modification and a	authority)					
X D. OTHER (Specify type of modification and a FAR 52.232-22	autionity)					
E. IMPORTANT: Contractor X is not,	is required to sign	n this document and return	copies	to the issuing	g office.	
			-			
14. DESCRIPTION OF AMENDMENT/MODIFIE where feasible.)	CATION (Organized	by OCF section headings, including sono	nation	contract subj	ect matter	
Modification Control Number: jpapa21576						
MODIFICATION OBLIGATION AMOUNT: \$437,5	00,000.00					
1. The purpose of this modification is to add in	cremental funding in t	he amount of \$437,500,000.00 via Sub		001 03.		
2. This change was requested by the requiring	g activity in order to n	neet mission goals				
3. As a result of this modification, the total fund	ded amount for this c	ontract was increased by \$437,500,0	00.00.	The total valu	e and all oth	ər
terms and conditions remain unchanged.						
Execution provided herein all terms and an dition of the t	aumont referenced in Iter (	A or 104 as hamtofree abanged	nged 1	in full fam	affect	
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.			r print)			
15A. NAME AND TITLE OF SIGNER (Type or print) 16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) (a) (b)			· Print)			
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNEI		RICA		16C	. DATE SIGNED
		BY			25	-Nov-2020
(Signature of person authorized to sign)		(Signature of Contracting Of	ficer)			
EXCEPTION TO SF 30 APPROVED BY OIRM 11-84	3	30-105-04			NDARD FO	RM 30 (Rev. 10-83)

# SUMMARY OF CHANGES

SECTION B - SUPPLIES OR SERVICES AND PRICES

# SUBCLIN 000103 is added as follows:

ITEM NO 000103 SUPPLIES/SERVICES QUANTITY UNIT UNIT PRICE AMOUNT \$0.00 ACRN AB @ \$437,500,000.00 FFP PR #0011579643 for 350,000 doses to be delivered NLT 31 December 2020 per bilateral agreement by KO & contractor on 24 Nov 2020. PURCHASE REQUEST NUMBER: 0011579643

NET AMT

\$0.00

\$437,500,000.00

ACRN AB CIN: GFEBS001157964300001

# SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Sch			
INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

# SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by \$437,500,000.00 from \$375,000,000.00 to \$812,500,000.00.

SUBCLIN 000103: Funding on SUBCLIN 000103 is initiated as follows:

ACRN: AB

CIN: GFEBS001157964300001

Acctng Data: 0212021202220400000665654255

6100.9000021001

Increase: \$437,500,000.00

Total: \$437,500,000.00

Cost Code: A5XAH

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1 CONTRACT ID CODE		PAGE OF PAGES
AMENDMENT OF SOLICITA	ATION/MODIF	ICATION OF CONTRACT	S 1		1 3	
2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO			5 PROJECT	NO (Ifapplicable)
P00005	02-Dec-2020	SEE SCHEDULE				
6 ISSUED BY CODE	W911QY	7 ADMINISTERED BY (Ifother than item 6)		COL	DE	
W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011		See Item 6				
8. NAME AND ADDRESS OF CONTRACTOR	No., Street, County, S	state and Zip Code)	94	A. AMENDMI	ENT OF SO	LICITATION NO.
ELL LLY AND COMPANY	(,,,					
1LLY CORPORATE CTR INDIANAPOLIS IN 46285			91	3. DATED (SE	SE ITEM I	1)
			X W	A. <u>MOD. OF</u> 911QY21C00	CONTRAC	T/ORDER NO.
				B. DATED (	SEE ITEM	13)
CODE 75602	FACILITY COD	E PPLIES TO AMENDMENTS OF SOLIO		7-Oct-2020		
The above numbered solicitation is amended as set forth				extended,	is not exte	nded
Offer must acknowledge receipt of this amendment prior					IS HOT CALC	nucu
(a) By completing Items 8 and 15, and returning	-	t; (b) By acknowledging receipt of this amendme		-	er submitted;	
or (c) By separate letter or telegram which includes a re					TO BE	
RECEIVED AT THE PLACE DESIGNATED FOR TH REJECTION OF YOUR OFFER If by virtue of this an					tor	
provided each telegramor letter makes reference to the					ter,	
12. ACCOUNTING AND APPROPRIATION DA	ATA (If required)					
See Schedule						
		O MODIFICATIONS OF CONTRACT T/ORDER NO. AS DESCRIBED IN IT				
A. THIS CHANGE ORDER IS ISSUED PURSU CONTRACT ORDER NO. IN ITEM 10A.	JANT TO: (Specify a	uthority) THE CHANGES SET FORTH	IN ITI	EM 14 ARE M	IADE IN T	HE
B. THE ABOVE NUMBERED CONTRACT/C office, appropriation date, etc.) SET FORT					as changes i	n paying
C. THIS SUPPLEMENTAL AGREEMENT IS	ENTERED INTO PU	RSUANT TO AUTHORITY OF:				
X D. OTHER (Specify type of modification and FAR 52.232-22	authority)					
E. IMPORTANT: Contractor X is not,	is required to sig	n this document and return	copies	s to the issuing	g office.	
14. DESCRIPTION OF AMENDMENT/MODIFI where feasible.) Modification Control Number: jpapa21578 MODIFICATION OBLIGATION AMOUNT: \$375,0	3	by UCF section headings, including solic	citation	/contract subje	ect matter	
1. The purpose of this modification is to add in	cremental funding in t	he amount of \$375,000,000.00 via Sub	bCLIN (	001 04.		
2. This change was requested by the requiring activity in order to meet mission goals						
3. As a result of this modification, the total funded amount for this contract w as increased by \$375,000,000.00 from \$812,500,000.00 to \$1,187,500,000.00. The total value and all other terms and conditions remain unchanged.						
Except as provided herein, all terms and conditions of the de	ocument referenced in Items	9A or 10A, as heretofore changed, remains uncha	nged and	l in full force and	effect	
15A. NAME AND TITLE OF SIGNER (Type or		16A. NAME AND TITLE OF CO	NTRA FFICER	CT ING OFFIC		or print)
15D CONTRACTOR/OFFEROR	150 DATE CONT			b) (6)	1.4	
15B. CONTRACT OR/OFFEROR	15C. DATE SIGNEI	D 16B UNITED STATES OF AME (b) (6) BY	KICA			C. DATE SIGNED 2-Dec-2020
(Signature of person authorized to sign)		(Signature of Contracting Of	ficer)			2 200-2020
EXCEPTION TO SF 30	3	80-105-04		STA	NDARD F	ORM 30 (Rev. 10-83)

EACEF HON IC	J 31 30
APPROVED BY	OIRM 11-84

Prescribed by GSA FAR (48 CFR) 53.243

# SUMMARY OF CHANGES

#### SECTION B - SUPPLIES OR SERVICES AND PRICES

# SUBCLIN 000104 is added as follows:

ITEM NO 000104 SUPPLIES/SERVICES QUANTITY UNIT UNIT PRICE AMOUNT 000104 ACRN AC @ \$375,000,000.00 FFP PR #0011580971 for 300,000 doses to be delivered NLT 31 January 2021 per bilateral agreement by KO & contractor on 24 Nov 2020. PURCHASE REQUEST NUMBER: 0011580971

 NET AMT
 \$0.00

 ACRN AC
 (b) (4)

 CIN: GFEBS001158097100001
 (b) (4)

# SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000104:       INSPECT AT       ACCEPT AT       ACCEPT BY         N/A       N/A       N/A       N/A			
INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

# SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by \$375,000,000.00 from \$812,500,000.00 to \$1,187,500,000.00.

SUBCLIN 000104:

Funding on SUBCLIN 000104 is initiated as follows:

ACRN: AC

CIN: GFEBS001158097100001

Acctng Data: 0212021202220400000665654255

6100.9000021001

Increase: \$375,000,000.00

Total: \$375,000,000.00

Cost Code: A5XAH

# W911QY-21-C-0016 Attachment 0001 OWS Security Requirements

Date: 26 October 2020 # of pages: 6

# Security Requirements

# Access and General Protection/Security Policy and Procedures

This standard language text is applicable to ALL employees working on critical information related to Operation Warp Speed (OWS), and to those with an area of performance within a Government controlled installation, facility or area. Employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The performer also shall provide all information required for background checks necessary to access critical information related to OWS, and to meet Government installation access requirements to be accomplished by installation Director of Emergency Services or Security Office. The workforce must comply with all personnel identity verification requirements as directed by the Government and/or local policy. In addition to the changes otherwise authorized by the changes 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 Pl	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 propo	security plan with their proposal to the Government for review and approval by Government security subject							
matter experts. The performan	nce of work under the contract will be in accordance with the approved security							
plan. The security plan will in	aclude the following processes and procedures at a minimum:							
	<ul> <li>organization chart and responsibilities</li> </ul>							
Security Administration	<ul> <li>written security risk assessment for site</li> </ul>							
	<ul> <li>threat levels with identification matrix (High, Medium, or Low)</li> </ul>							

	enhanced security procedures during elevated threats
	<ul> <li>liaison procedures with law enforcement</li> </ul>
	<ul> <li>annual employee security education and training program</li> </ul>
	<ul> <li>policies and procedures</li> </ul>
Personnel Security	candidate recruitment process
	<ul> <li>background investigations process</li> </ul>
	<ul> <li>employment suitability policy</li> </ul>
	<ul> <li>employee access determination</li> </ul>
	<ul> <li>rules of behavior/ conduct</li> </ul>
	<ul> <li>termination procedures</li> </ul>
	<ul> <li>non-disclosure agreements</li> </ul>
Physical Security Policies	<ul> <li>internal/external access control</li> </ul>
and Procedures	<ul> <li>protective services</li> </ul>
	<ul> <li>identification/badging</li> </ul>
	<ul> <li>employee and visitor access controls</li> </ul>
	<ul> <li>parking areas and access control</li> </ul>
	<ul> <li>perimeter fencing/barriers</li> </ul>
	<ul> <li>product shipping, receiving and transport security procedures</li> </ul>
	<ul> <li>facility security lighting</li> </ul>
	restricted areas
	• signage
	intrusion detection systems
	alarm monitoring/response
	closed circuit television
	<ul> <li>product storage security</li> </ul>
	<ul> <li>other control measures as identified</li> </ul>
Information Security	<ul> <li>identification and marking of sensitive information</li> </ul>
-	access control
	storage of information
	document control procedures
	retention/ destruction requirements
Information	<ul> <li>intrusion detection and prevention systems</li> </ul>
Technology/Cyber Security	threat identification
Policies and Procedures	• employee training (initial and annual)
	encryption systems
	<ul> <li>identification of sensitive information/media</li> </ul>
	<ul> <li>password policy (max days 90)</li> </ul>
	<ul> <li>lock screen time out policy (minimum time 20 minutes)</li> </ul>
	removable media policy
	laptop policy
	<ul> <li>removal of IT assets for domestic/foreign travel</li> </ul>
	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
	<ul> <li>property accountability</li> </ul>
2. Site Security Maste	

Description: The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; IT Server Room; Product Storage Freezer/Room; and bio-containment laboratories.

# 3. Site Threat / Vulnerability / Risk Assessment

Description: The partner facility shall provide a written risk assessment for the facility addressing: criminal threat, including crime data; foreign/domestic terrorist threat; industrial espionage; insider threats; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies. The assessment should be updated annually.

4. Physical Security	
Description:	
Closed Circuit Television (CCTV) Monitoring	<ul> <li>a) Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored.</li> <li>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.</li> </ul>
	<ul> <li>c) Video recordings must be maintained for a minimum of 30 days.</li> <li>d) CCTV surveillance system must be on emergency power backup.</li> <li>e) CCTV coverage must include entry and exits to critical facilities,</li> </ul>
	<ul><li>perimeters, and areas within the facility deemed critical to the execution of the contract.</li><li>f) Video recordings must be maintained for a minimum of 30 days.</li><li>g) CCTV surveillance system must be on emergency power backup.</li></ul>
Facility Lighting	<ul> <li>a) Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings.</li> <li>b) Lighting must have emergency power backup.</li> <li>c) Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.</li> </ul>
Shipping and Receiving	<ul> <li>a) Must have CCTV coverage and an electronic access control system.</li> <li>b) Must have procedures in place to control access and movement of drivers picking up or delivering shipments.</li> <li>c) Must identify drivers picking up Government products by government issued photo identification.</li> </ul>
Access Control	<ul> <li>a) Must have an electronic intrusion detection system with centralized monitoring.</li> <li>b) Responses to alarms must be immediate and documented in writing.</li> <li>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.).</li> <li>d) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas.</li> <li>e) Must have a system that provides a historical log of all key access transactions and kept on record for a minimum of12 months.</li> <li>f) Must have procedures in place to track issuance of access cards to employee sand the ability to deactivate cards when they are lost or an employee leaves the company.</li> <li>g) Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of 12 months.</li> <li>h) Should have written procedures to prevent employee piggybacking access</li> </ul>

[	
	<ul> <li>to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for</li> </ul>
	access.
	<ul><li>j) Must have a written manual key accountability and inventory process.</li><li>k) Physical access controls should present a layered approach to critical</li></ul>
	assets within the facility.
Employee/Visitor	a) Should issue company photo identification to all employees.
Identification	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.
	<ul><li>d) Visitors should be logged in and out of the facility and should be escorted</li></ul>
	by an employee while on the premises at all times.
Security Fencing	Requirements for security fencing will be determined by the criticality of the
Security I enoung	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	a) Must have in-service training program.
Operations	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 Operation 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
	<ul><li>Officer that attended the meeting must be documented.</li><li>c) Implement procedures for receiving and disseminating threat</li></ul>
	information.
Training	a) Conduct new employee security awareness training.
Training	<ul><li>b) Conduct and maintain records of annual security awareness training.</li></ul>
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	a) Detailed policies and procedures concerning hiring and retention of
Standards	employees, employee conduct, and off boarding procedures.
	<ul> <li>b) Off Boarding procedures should be accomplished within 24 hour of employee leaving the company. This includes termination of all network</li> </ul>
	access.
7. Information Securi	
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)	
	C)	to know.
Document Destruction		ents must be destroyed using approved destruction measures (i.e,
		rs/approved third party vendors / pulverizing / incinerating).
8. Information Techno Description:	ology & C	Cybersecurity
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
	(h	rooms with electronic access controls.
Training	d) a)	Limit access to/ verify access to use of external information systems. Ensure that personnel are trained and are made aware of the security risks
Training	a)	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.
Configuration Management	a) 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
Lead Acat D	、 、	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.
		capaonity annually.

Media and Information	a)	Protect information system media, both paper and digital.
Protection	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	a)	Limit access to information systems, equipment, and the respective
Protection	1)	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
	,t	systems.
	d)	Protect information systems against environmental hazards.
Notes 1 Desta di su	e)	Escort visitors and monitor visitor activity.
Network Protection		intrusion prevention and detection technology with immediate analysis
	capabili	ties.
9. Transportation Sec		
		s must be implemented to protect materials while in transit from theft,
destruction, manipulation, or		
Drivers	a)	Drivers must be vetted in accordance with Government Personnel
	1	Security Requirements.
		Drivers must be trained on specific security and emergency procedures.
		Drivers must be equipped with backup communications.
	d)	
		Government product.
	e)	Drivers must never leave Government products unattended, and two
		drivers may be required for longer transport routes or critical products
	0	during times of emergency.
	f)	Truck pickup and deliveries must be logged and kept on record for a
Transmost Desites		minimum of 12 months.
Transport Routes	a)	Transport routes should be pre-planned and never deviated from except
	<b>b</b> )	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
Product Scourity		delay or disrupt transport. Government products must be secured with tamper resistant seals during
Product Security	a)	transport, and the transport trailer must be locked and sealed.
		<ul> <li>Tamper resistant seals must be verified as "secure" after the product is placed in the temperaturchicle</li> </ul>
	1)	product is placed in the transport vehicle.
	(0	Government products should be continually monitored by GPS
		technology while in transport, and any deviations from planned routes
		should be investigated and documented. Contingency plans should be in place to keep the product secure during
	c)	emergencies such as accidents and transport vehicle breakdowns.
10 Security Departing	Doguine	
10. Security Reporting	-	
		notify the Government Security Team within 24 hours of any activity or ed security standards or indicates the loss or theft of government products.
		with these incidents will be documented in writing for government
The facts and circumstances a	issociated	with these merdents 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.

\_\_\_\_

# W911QY-21-C-0016 Exhibit A Contract Data Requirements List CDRLs

Date: 26 October 2020 # of pages: 32

CONTRACT DATA REQUIREMENTS LIST (1 Data Item)						Form Approved OMB No. 0704-0188				
data sources, gatherir other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information dents should be aware th	ata needed, a n, including s nat notwithsta y valid OMB c	nd completing and suggestions for rec anding any other pro control number. Ple	reviewing the collection of ducing the burden, to the ovision of law, no person s ease do not return your for	information. Department hall be subject	g the time for reviewing ins Send comments regarding of Defense, Executive Se ct to any penalty for failing ve organization. Send com	this burder rvices Dire	n estimat ctorate with a co	te or any	
A. CONTRACT L	INE ITEM NO. 001	B. EXHIE	ыт А	C. CATEGORY: TDP X TM	oTU	150				
D. SYSTEM/ITEM			E. CONTRAC							
	Therapeutics		W911	QY21C0016		Lilly				
1. DATA ITEM NO.	2. TITLE OF DATA ITEM		NC /		3. SUBTITL	E				17. PRICE GROUP
A001	Post Award Telec	onference	Minutes							
	Acquisition Document No	p.)	5. CONTRACT RE			6. REQUIRING OFFICE				18. ESTIMATED TOTAL PRICE
7. DD 250 REQ	ADMN-81505 9. dist statement	10. FREQU	ENCY	SOW 12. DATE OF FIRST SU	PMISSION					I
7. 00 200 NEQ	REQUIRED		remarks	see remar				. COPIES	6	
8. APP CODE		11. AS OF	DATE	13. DATE OF SUBSEQU SUBMISSION	JENT	a. ADDRESSEE	Draft	Fir	nal	
16. REMARKS				see remar	ks	BARDA		Reg	Repro	
	all complete an init	ial telecon	ference after as	preement award		JPEO CBRND	1			
	ties for the next 30									
2. Discuss agend	la items for the post	t-award Ki	ckoff Meeting	(A002)						
Within one weel	k of Agreement awa	ard								
				e number at least 3 b						
				RDA will supply on						
<ul> <li>AOR edits/app least 2 business</li> </ul>		Awardee t	o distribute age	enda prior to meeting	by at					1
	-	s to AOR	within 3 busine	ess days after the mee	eting					1
• AOR reviews,	comments and appr	roves minu	tes within 10 b	ousiness days						
										Ì
										1
							_			1
										1
										1
							_			
										1
										1
G. PREPARED B	Y		H. DATE	I. APPROVE	D BY	15. TOTAL	► 2 J. DA	0 TE	0	
	-									1
(b) (6)	À			(b) (6)	v					
DD FORM 14	23-1, FEB 200	1	PREV	IOUS EDITION MAY	BE USED.	Page _	<u>1</u> of 3 Adob		Pages sional 8.0	

CONTRACT DATA REQUIREMENTS LIST (1 Data Item)						Form Approved OMB No. 0704-0188				
data sources, gatherir other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information idents should be aware th	ata needed, ar n, including s hat notwithsta y valid OMB c	nd completing and in suggestions for red anding any other pro ontrol number. Ple	reviewing the collection of ucing the burden, to the ovision of law, no person s ase do not return your for	information. Department hall be subject	g the time for reviewing inst Send comments regarding t of Defense, Executive Serv t to any penalty for failing to ve organization. Send comp	this burder vices Dire comply v	n estimat ctorate with a co	te or any	
A. CONTRACT L	INE ITEM NO.	B. EXHIE	BIT A	C. CATEGORY: TDP X TM	отн	FR				
D. SYSTEM/ITEM			E. CONTRAC			RACTOR				
	Therapeutics		W911	QY21C0016		Lilly				17. PRICE GROUP
1. DATA ITEM NO. A002	2. TITLE OF DATA ITEN Kickoff Meeting		d Minutes		3. SUBTITL	E				17. PRICE GROUP
	Acquisition Document No ADMN-81505	D.)	5. CONTRACT RE	FERENCE		6. REQUIRING OFFICE	RDA			18. ESTIMATED TOTAL PRICE
7. DD 250 REQ	9. DIST STATEMENT	10. FREQU	ENCY	12. DATE OF FIRST SU	BMISSION	14. DISTRIB				
	REQUIRED	see	remarks	see remar	ks		b	. COPIES	s	
8. APP CODE		11. AS OF	DATE	13. DATE OF SUBSEQU SUBMISSION See remar		a. ADDRESSEE	Draft		nal	
16. REMARKS				see reman	4.5	BARDA	1	Reg	Repro	
The Awardee sh	all complete a Kick	off meetin	g after agreeme	ent award • Within a	month of	JPEO CBRND	1			
<u> </u>	d, pending concurre	-	•							
	-	nd agenda a	at least 5 busine	ess days in advance o	f site visit					
or virtual meetin • AOR edits/app	-	Awardee t	o distribute age	nda prior to meeting	by at					
least 3 business		1100000	o albanoate age	indu prior to meeting	oyat					
	•	s to AOR	within 3 busine	ess days after the mee	ting					
• AOR reviews,	comments, and app	roves mim	ites within 10 l	ousiness days						
							-			
G. PREPARED B	v		H. DATE	I. APPROVE	DBY	15. TOTAL	· 2 J. DA	0 TE	0	
S. THEFANLU D	•			I. APPROVE						
(b) (6)	λ		•	(b) (6)						
DD FORM 14	23-1, FEB 200	1	PREVI	OUS EDITION MAY	BE USEĎ.	Page	2 of 3	32	Pages	
							Adol	e Profes	sional 8.0	

CONTRACT DATA REQUIREMENTS LIST (1 Data Item)						Form Approved OMB No. 0704-0188				
data sources, gatherin other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information idents should be aware th	ata needed, a n, including s hat notwithsta y valid OMB c	nd completing and i suggestions for red anding any other pro control number. Ple	reviewing the collection of ucing the burden, to the ovision of law, no person s ase do not return your for	information. Department hall be subject	g the time for reviewing ins: Send comments regarding of Defense, Executive Ser t to any penalty for failing t ve organization. Send comp	this burder vices Dire to comply v	n estima ctorate with a co	te or any	
A. CONTRACT I	INE ITEM NO.	B. EXHIE	BIT	C. CATEGORY: TDP X TM						
D. SYSTEM/ITE	001 M		A E. CONTRAC							
-	Therapeutics		W911	QY21C0016		Lilly				 
1. DATA ITEM NO.	2. TITLE OF DATA ITEM				3. SUBTITL	E				17. PRICE GROUP
A003	Teleconference M	linutes								
	Acquisition Document No ADMN-81505	o.)	5. CONTRACT RE	FERENCE SOW		6. REQUIRING OFFICE	RDA			18. ESTIMATED TOTAL PRICE
7. DD 250 REQ	9. DIST STATEMENT	10. FREQU	ENCY	12. DATE OF FIRST SU	BMISSION		BUTION			
	REQUIRED		e remarks	see remar			t	. COPIE	S	
8. APP CODE		11. AS OF	DATE	SUBMISSION SUBMISSION		a. ADDRESSEE	Draft	Fi Reg	Repro	
16. REMARKS				see reman	K5	BARDA	1	neg	nepro	
				ks, with BARDA to		JPEO CBRND	1			
				e increased with agre				<u> </u>		
	than 2 business day			et • Awardee provide	es agenda					
			-	nda prior to meeting			+			
	butes agenda and p	resentation	materials if ne	eded at least 24 hour	s in					
advance	ides mosting minute		within 2 husing	ss days of the meetin						
-	comments, and app			•	ig					
	lude distribution and			ý			+			
								<u> </u>		
							+			
								<u> </u>		
							+			
							_			
						15. TOTAL	• 2	0	0	
G. PREPARED B	Y		H. DATE	I. APPROVE	D BY		J. DA		V	
	(						.			
	22 1 EED 200	1	DDEV/	(b) (6) OUS EDITION MAY	BE LISED	Denti	3 of 3	30	Perce	
	23-1, FEB 200		FNEVI		DE OBED.	Page _			Pages	

CONTRACT DATA REQUIREMENTS LIST (1 Data Item)						Form Approved OMB No. 0704-0188				
data sources, gatherin other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information idents should be aware th	ata needed, and n, including s at notwithsta valid OMB c	nd completing and suggestions for red anding any other pro- control number. Ple	reviewing the collection of lucing the burden, to the ovision of law, no person s ase do not return your for	information. Department hall be subject	g the time for reviewing inst Send comments regarding of Defense, Executive Ser to any penalty for failing to ve organization. Send comp	this burder vices Dire cocomply v	n estimat ctorate vith a co	te or any	
A. CONTRACT I	_	B. EXHIE		C. CATEGORY:	отн	FR				
D. SYSTEM/ITER			E. CONTRAC			RACTOR				
1. DATA ITEM NO.	Therapeutics 2. TITLE OF DATA ITEM	-	W911	QY21C0016	3. SUBTITL	Lilly				17. PRICE GROUP
A004	Quarterly Meeting				3. SUBTIL	E				
	Acquisition Document No -ADMN-81505	.)	5. CONTRACT RE	FERENCE		6. REQUIRING OFFICE	RDA			18. ESTIMATED TOTAL PRICE
7. DD 250 REQ	9. DIST STATEMENT	10. FREQU	ENCY	12. DATE OF FIRST SU	BMISSION	14. DISTRIE	BUTION			
	REQUIRED		remarks	see remar			b	. COPIES		
8. APP CODE		11. AS OF	DATE	SUBMISSION SUBMISSION		a. ADDRESSEE	Draft	Fi Reg	nal Repro	
16. REMARKS	•					BARDA	1			
	-			ecurring teleconferen		JPEO CBRND	1			
				er in Washington D. etings shall alternate						
				ngs will be used to di			_			1
-				leliverables described			_			
	signs, technical, reg	-	-							1
			-	ess days, and present	ation					
materials at leas	t 3 business days in	advance o	f site visit							
		Awardee t	o distribute age	enda prior to meeting	by at					
least 3 business	-									
-	-			ess days after the mee	eting		_			1
• AOK reviews,	comments, and appr	roves min	utes within 10 t	ousiness days						
							-			
										1
										1
							_			
							_			1
							_			
							_			
									+	
									+	
									+	
						15. TOTAL	• 2	0	0	
G. PREPARED B	Y		H. DATE	I. APPROVE	D BY		J. DA	TE		
(b) $(c)$			∎∣				.			1
(0) (0)										
DD FORM 14	123-1, FEB 200	1	PREVI	OUS EDITION MAY	BE USED.	Page _	4 of 3 Adob		Pages sional 8.0	

	Form Appro OMB No. 07											
data sources, gatherir other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information idents should be aware th	ata needed, and n, including s hat notwithsta y valid OMB c	nd completing and suggestions for red anding any other pro control number. Ple	reviewing the collection of lucing the burden, to the ovision of law, no person s ase do not return your for	information. Department hall be subject	g the time for reviewing instr Send comments regarding ti of Defense, Executive Serv t to any penalty for failing to ve organization. Send comple	ices Dire comply y	n estimat ctorate with a co	e or any			
A. CONTRACT L	-	B. EXHIE		C. CATEGORY: TDP X TM	отн	ED						
D. SYSTEM/ITEM			RACTOR									
	Therapeutics		Lilly				17. PRICE GROUP					
1. DATA ITEM NO. A005	EDA Mastina Minister											
	Acquisition Document No	o.)	5. CONTRACT RE	FERENCE		6. REQUIRING OFFICE				18. ESTIMATED		
	ADMN-81505	SOW		BARDA				TOTAL PRICE				
7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQU	ency remarks	12. DATE OF FIRST SU see remar		14. DISTRIB	b. COPIES					
8. APP CODE		11. AS OF	DATE 13. DATE OF SUBSEQUEN					Fir		1 <b>B</b>		
				SUBMISSION see remar	ks		Draft Reg Rep		Repro			
16. REMARKS						BARDA	1					
All formal and in	nformal communica	ations with	the FDA shou	ld be provided to BA	RDA	JPEO CBRND	1					
Contractor sha	11 notify BARDA o	funcoming	FDA meeting	within 24 hours of s	heduling							
				urrence for ad hoc m								
				draft minutes and fin								
of any meeting v	with the FDA to BA	ARDA with	in 2 business d	ays of receipt								
								<u> </u>				
								<u> </u>		l		
						15. TOTAL	2	0	0			
G. PREPARED B	Y		H. DATE	I. APPROVE	D BY	-	J. DA	TE	-			
	·											
				(b) (6)								
ор ғокм 14	23-1, FEB 200	11	PREVI	OUS EDITION MAY	BE USED.	Page	5 of 3 Adob		Pages sional 8.0			

	Form Approved OMB No. 0704-0188										
data sources, gatherin other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information dents should be aware th	ata needed, a n, including s nat notwithsta v valid OMB c	nd completing and i suggestions for red anding any other pro control number. Ple	reviewing the collection of lucing the burden, to the ovision of law, no person si ase do not return your for	information. Department hall be subject	g the time for reviewing ins Send comments regarding of Defense, Executive Se t to any penalty for failing t we organization. Send com	this burder rvices Dire to comply v	n estima ctorate with a co	te or any		
A. CONTRACT I	_	B. EXHIE		отн	ER						
D. SYSTEM/ITER	N		RACTOR								
1. DATA ITEM NO.	Therapeutics 2. TITLE OF DATA ITEN	3. SUBTITL	Lilly E				17.	PRICE GROUP			
A006	A006 Daily check in with project staff for COVID-19 Agreement										
4. AUTHORITY (Data Acquisition Document No.) DI-ADMN-81505			5. CONTRACT RE	FERENCE		6. REQUIRING OFFICE BA	RDA				ESTIMATED TOTAL PRICE
7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQU	JENCY 12. DATE OF FIRST SUB		BMISSION	14. DISTRI	BUTION				
	in Euronice		remarks	see remar			t	D. COPIE			
8. APP CODE		11. AS OF	DATE	SUBMISSION See remark		a. ADDRESSEE	Draft	Fi Reg	Repro		
16. REMARKS				see remain	19	BARDA	1	neg	nepro		
Upon request of	the Government, th	e contract	or shall particip	ate in a daily check-	n update	JPEO CBRND	1				
				et staff as needed (via							
	· · · · · · · · · · · · · · · · · · ·	~~		nelude but are not lim							
•	s changes, manufact	uring and	or/distribution	problems that will af	fect						
delivery.							_	<u> </u>			
Daily check-ins	may occur on week	days, excl	uding federal h	olidays. Upon reque	st of the		_				
-	•		-	federal holidays, prov							
least 24 hours' n							-				
-		be required	l but may be pro	ovided on an ad hoc	oasis as						
data or circumst											
-	l be required for the	meeting					_				1
-	inutes are required	mail undat	as fallowing on	y call or in lieu of a	all her						
2PM for that day	-	man updat	es following an	ly call of in fieu of a (	an by		_				
21 Mi for that da	,						_				
							_				
							_				
							_				
							_				
								<b> </b>			
							_				
						15. TOTAL	• 2	0	0		
G. PREPARED B	Y		H. DATE	I. APPROVE	D BY		J. DA		v		
	I										
(b) (6)	L.			(b) (6)							
DD FORM 14	23-1, FEB 200	1	PREVI	OUS EDITION MAY	BE USED.	Page _	6 of 3 Adol		Pages sional 8.0	•	

CONTRACT DATA REQUIREMENTS LIST (1 Data Item)						Form Approved OMB No. 0704-0188					
data sources, gatherir other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information idents should be aware th	ta needed, and n, including s at notwithsta valid OMB c	nd completing and re suggestions for redu anding any other prov ontrol number. Plea	eviewing the collection of ucing the burden, to the vision of law, no person sl use do not return your forr	information. Department hall be subject	g the time for reviewing inst Send comments regarding of Defense, Executive Ser t to any penalty for failing t ve organization. Send comp	this burder vices Dire o comply v	n estima ctorate with a co	te or any		
A. CONTRACT L	INE ITEM NO. 001	IER									
D. SYSTEM/ITEM		RACTOR									
	Therapeutics		W9110	Lilly				17. PRICE GR	0.110		
1. DATA ITEM NO. A007	2. TITLE OF DATA ITEM 3. SUBTITLE Monthly Progress Reports										JUP
4. AUTHORITY (Data	.)	ERENCE	I	6. REQUIRING OFFICE				18. ESTIMATE TOTAL PR			
7. DD 250 REQ	-MISC-80711 9. dist statement	10. FREQU			MISSION	BARDA 14. DISTRIBUTION					
	REQUIRED	see	remarks	see remarks			b. COPIES				
8. APP CODE		11. AS OF	DATE	13. DATE OF SUBSEQU SUBMISSION see remar		a. ADDRESSEE	Draft	Fi Reg	inal Repro		
16. REMARKS						BARDA	1				
	submission of all sli		ta presented at t	the biweekly		JPEO CBRND	1				
	ve as the monthly re consists of a summa		tity of product	delivered, when and	location			<u> </u>			
of the delivery.		ny or quar	inty of product								
		l on or bef	ore the 20th day	of the month cover	ing the						
preceding month	1										
									_		
								<u> </u>			
						15. TOTAL	2	0	) 0		
G. PREPARED B	Y		H. DATE	I. APPROVE	) BY		J. DA				
$(\mathbf{b})$ $(\mathbf{c})$	,										
	23-1, FEB 200	1	PREV/IC	(b) (6) DUS EDITION MAY I	BE LISED	Dage	7 cf 2	22	Pagas		
	23-1, FEB 200	•	THEVIL		DE UGED.	Page _	7 of 3 Adol		Pages		

CONTRACT DATA REQUIREMENTS LIST (1 Data Item)						Form Approved OMB No. 0704-0188						
data sources, gatherin other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information	ata needed, a n, including s nat notwithsta v valid OMB c	nd completing and suggestions for red anding any other pro control number. Ple	reviewing the collection of lucing the burden, to the ovision of law, no person s ase do not return your for	information. Department	g the time for reviewing ins Send comments regarding of Defense, Executive See at to any penalty for failing t ve organization. Send comp	this burder rvices Dire	n estimat ctorate	te or any			
A. CONTRACT I	LINE ITEM NO.	IER										
D. SYSTEM/ITE	001 <b>V</b>											
	Therapeutics	Lilly		17. PRICE GROUP								
1. DATA ITEM NO. A 008	A008     2. TITLE OF DATA ITEM     3. SUBTITLE											
4. AUTHORITY (Data Acquisition Document No.) 5. CONTRACT REFERENCE 6. REQUIRING OFFICE												
DI-MISC-80711 SOW							RDA			18. ESTIMATED TOTAL PRICE		
7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQU	ency remarks	12. DATE OF FIRST SU see remar		14. DISTRI						
8. APP CODE		11. AS OF		13. DATE OF SUBSEQU SUBMISSION		a. ADDRESSEE	Draft	. COPIES	nal			
16. REMARKS				see remar	ks	BARDA	_	Reg	Repro			
	ts shall be cross-refe	erenced to	the Work Brea	kdown Structure (W	BS) and	JPEO CBRND						
Statement of Wo	ork (SOW).			-								
As applicable, a	n Executive Summa	ary highlig	hting the progr	ess, issues and releva	nt		_					
manufacturing,	non-clinical, clinical	l and regul	latory activities	. The Executive Sum	umary							
should highlight limited to 2 page		for that re	porting period	and resolution appro	ach;							
		ed upon th	e completion o	f each milestone and	include							
		R and AO	will review the	monthly reports wit	h the					1		
Awardee and pro • Awardee shall		sions of re	ports within 10	) business days after	receiving							
BARDA comme	-			2	5							
								<u> </u>				
										1		
										1		
									+			
						1						
						15. TOTAL	• 2	0	0			
G. PREPARED B	Y		H. DATE	I. APPROVE	D BY		J. DA	-	U			
(b) (C)	<u>[</u>											
	23-1, FEB 200	1	PREVI	OUS EDITION MAY	BE LISED	Dage	8 of 3	32	Pagas			
	23-1, FED 200	•	THEVI	SSS EDITION WAT	DE OULD.	Page _			Pages sional 8.0			

	CONTRACT	DATA R (1 Data		ITS LIST		Form Appro OMB No. 0		88			
data sources, gatherir other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information dents should be aware th	ata needed, an n, including s nat notwithsta v valid OMB c	nd completing and suggestions for red anding any other pro- control number. Ple	reviewing the collection of lucing the burden, to the ovision of law, no person s ase do not return your for	information. Department hall be subject	g the time for reviewing ins Send comments regarding of Defense, Executive Se t to any penalty for failing t we organization. Send com	this burder rvices Director to comply v	n estimat ctorate vith a co	te or any		
A. CONTRACT L	INE ITEM NO.	B. EXHIE	BIT	C. CATEGORY: TDP X TM	0.711	-	-				
D. SYSTEM/ITEM	001 VI		A E. CONTRAC								
	Therapeutics		W911	QY21C0016		Lilly					
1. DATA ITEM NO. А009	2. TITLE OF DATA ITEN Draft Technical Pr		port		3. SUBTITL	E				17. PK	ICE GROUP
	Acquisition Document No -MISC-80711	p.)	5. CONTRACT RE	FERENCE		6. REQUIRING OFFICE	RDA				TIMATED
7. DD 250 REQ	9. DIST STATEMENT	10. FREQU	ENCY	12. DATE OF FIRST SU	BMISSION		BUTION				
	REQUIRED		remarks	see remar	ks			. COPIES	6		
8. APP CODE		11. AS OF	DATE	13. DATE OF SUBSEQU SUBMISSION See remar		a. ADDRESSEE	Draft	Fir Reg	nal Repro		
16. REMARKS						BARDA	1				
				tion of the work perf		JPEO CBRND	1				
				letail to fully describe							
				n a timeline of origin actual progress attai							
-				es and milestones that							
				all be duly marked a							
• The Draft Tech	mical Progress Rep	ort shall be	e submitted 60	calendar days before	the end of						
the PoP and the				the completion date							
PoP • AOR will prov	ide feedback on dra	uft report w	vithin 15 calend	lar days of receipt, w	hich the						
-	onsider incorporatin	-		ai days of receipt, w	inen the						
	1	0	-						1		
										1	
										1	
G. PREPARED B	v		H. DATE	I. APPROVE	DBY	15. TOTAL	► 2 J. DA	0 TE	0		
G. FREPARED D	•		II. DAIL				U. DA			1	
(b) (6)	Å			(b) (6)							
DD FORM 14	23-1, FEB 200	1	PREVI	OUS EDITION MAY	BE USED.	Page _	9 of 3 Adob		Pages sional 8.0		

	CONTRACT	DATA R (1 Data		ITS LIST		Form Appro OMB No. 0		88		
data sources, gatherin other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information idents should be aware th	ata needed, a n, including s hat notwithsta y valid OMB c	nd completing and suggestions for red anding any other pro control number. Ple	reviewing the collection of lucing the burden, to the ovision of law, no person s ase do not return your for	information. Department hall be subject	g the time for reviewing ins Send comments regarding of Defense, Executive Se t to any penalty for failing ve organization. Send com	this burder rvices Dire to comply v	n estimat ctorate with a co	te or any	
A. CONTRACT I	LINE ITEM NO. 001	B. EXHIE	ыт А	C. CATEGORY:	отн	FR				
D. SYSTEM/ITER			E. CONTRAC			RACTOR				
1. DATA ITEM NO.	Therapeutics 2. TITLE OF DATA ITEN		W911	QY21C0016	3. SUBTITL	Lilly				17. PRICE GROUP
A010	Final Technical P		port		3. SUBTIL	E				
	Acquisition Document No -MISC-80711	p.)	5. CONTRACT RE	FERENCE		6. REQUIRING OFFICE	RDA			18. ESTIMATED TOTAL PRICE
7. DD 250 REQ	9. DIST STATEMENT	10. FREQU	ENCY	12. DATE OF FIRST SU	BMISSION		BUTION			
	REQUIRED	see	e remarks	see reman			t	. COPIES	6	
8. APP CODE		11. AS OF	DATE	13. DATE OF SUBSEQU SUBMISSION See remai		a. ADDRESSEE	Draft	Fir Reg	Repro	
16. REMARKS						BARDA	1			
		-	-	received from BARI		JPEO CBRND	1			
		-		agreement PoP. The e final report shall b						
				a summary (not to e						
· -	ct delivery and dist	ribution ac	hieved during t	he performance of th	le					
Agreement										
	-		-	s submitted through	ut the					
period of perform	mance and include a	an overarcl	hing executive	summary.						
							_			
								<u> </u>		
G. PREPARED B	v		H. DATE	I. APPROVE		15. TOTAL	► 2 J. DA		0	
G. PREPAKED B			n. DATE		זסט		J. DA	IIE .		
(b) (6)	Å			(b) (6)						
DD FORM 14	23-1, FEB 200	1	PREVI	OUS EDITION MAY	BE USED.	Page _	10 of Adol		Pages sional 8.0	

	CONTRACT	DATA R (1 Data		ITS LIST			orm Approv MB No. 07		88			
data sources, gatherin other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information indents should be aware th	ata needed, a n, including s nat notwithsta y valid OMB c	nd completing and i suggestions for red anding any other pro control number. Ple	erage 110 hours per respo reviewing the collection of ucing the burden, to the pvision of law, no person s ase do not return your for	information. Department hall be subject	Send commen of Defense, E t to any penalt	ts regarding th xecutive Servi y for failing to	ices Dire comply v	n estimat ctorate vith a co	te or any		
A. CONTRACT I	LINE ITEM NO.	B. EXHIE	BIT	C. CATEGORY:	0.711				ted form to the			
D. SYSTEM/ITE	001 M		A E. CONTRAC			RACTOR						
	Therapeutics			QY21C0016			Lilly					
1. DATA ITEM NO.	2. TITLE OF DATA ITEN				3. SUBTITL	E						17. PRICE GROUP
A011	Product Developm Reports	nent Sourc	e Material and	Manufacturing				BARDA ISTRIBUTION b. COPIES Final				
	Acquisition Document No I-TCSP-82040	p.)	5. CONTRACT RE	FERENCE SOW		6. REQUIRING		DA				18. ESTIMATED TOTAL PRICE
7. DD 250 REQ	9. DIST STATEMENT	10. FREQU	ENCY	12. DATE OF FIRST SU	BMISSION	14.		b. COPIES				
	REQUIRED	see	remarks	see remar						6		
8. APP CODE		11. AS OF	DATE	13. DATE OF SUBSEQU SUBMISSION See remar		a. ADDF	ESSEE			1		
16. REMARKS				see remain	4.5	BARDA				Repro		
The contractor s	shall submit a detaile	ed spreads	heet regarding o	critical project materi	ials that	JPEO CBR	ND					
				ces, and manufacturi	- ·							
				raw and processed m anufacturing sites; an								
•••	n-clinical and clinic	-		anuracturing sites, an	d location							
	-			acturing dose tracking	-							
	-		-	Cemplates" or similar	•							
-	ibmit Product Devel			product for clinical tr Report	ial use. •							
	of Agreement awar	-										
	s of substantive cha		nade to sources	and/or materials								
o Or on the 6th r	month contract anni	versary.										
				during manufacturin								
		-		olic Health Emergence	-							
	-			rable submission with n advance of comme								
				erations begins manu								
• The Governm	ent will provide wri	itten comm	ents to the Pro	duct Development So	ource							
			-	after the submission								
<ul> <li>If corrective ac BARDA in writ</li> </ul>		ed, contrac	tor must addres	s all concerns raised	by							
	0	Material re	enort to be subr	nitted via spreadshee	t: Dose							
	-		-	.g. XML or JSON) a	-							
to by USG and c	company.										İ	
											Ľ	
						15. TOTAL	<b>→</b>	2	0	0		
G. PREPARED B	Y		H. DATE	I. APPROVE	D BY	•		J. DA				
(b) (6)	j			(b) $(c)$								
DD FORM 14	123-1, FEB 200	1	PREVI	OUS EDITION MAY	BE USED.		Page	11 of	32	Pages	3	

Adobe Professional 8.0

	CONTRACT	DATA R (1 Data		ITS LIST		Form Appro OMB No. 0		88		
data sources, gatherir other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information dents should be aware th	ata needed, au n, including s hat notwithsta y valid OMB c	nd completing and suggestions for red anding any other pro control number. Ple	reviewing the collection of lucing the burden, to the ovision of law, no person s ase do not return your for	information. Department hall be subject	g the time for reviewing ins: Send comments regarding of Defense, Executive Ser t to any penalty for failing t ve organization. Send comp	this burder vices Dire to comply v	n estimat ctorate with a co	te or any	
A. CONTRACT L	INE ITEM NO. 001	B. EXHIE	ыт А	C. CATEGORY:	отн	ER				
D. SYSTEM/ITEM	M		E. CONTRAC			RACTOR				
1. DATA ITEM NO.	Therapeutics 2. TITLE OF DATA ITEN		W911	QY21C0016	3. SUBTITL	Lilly				17. PRICE GROUP
A012	Contractor Locati				3. SUBTIL	E				
	Acquisition Document No		5. CONTRACT RE			6. REQUIRING OFFICE				18. ESTIMATED
	or format acceptal 9. DIST STATEMENT			SOW			RDA			TOTAL PRICE
7. DD 250 REQ	REQUIRED	10. FREQU	ency eremarks	12. DATE OF FIRST SU see remar		14. DISTRI		. COPIES		
8. APP CODE		11. AS OF		13. DATE OF SUBSEQU		a. ADDRESSEE	Draft	-	nal	· <b>·</b>
				see remar	ks			Reg	Repro	
16. REMARKS	hall submit datailad	l data naca	ndina la astisna	where work will be p	aufamaad	BARDA	1			
		-	-	d work performed pe		JPEO CBRND	1			
to include sub-av	-	sses, point	s or contact, an	a nom periorma p						
	submit Work Locati	-								
	ess days of Agreem ness days after a su			hilities abance						
	•		-	performed supports r	nedical					
	•		-	been declared a Publ						
	-	r a Public I	Health Emerge	ncy of International	Concern					
(PHEIC) by the	WHO									
							_			
							_			
							_			
							-			
									──	
							-	<u> </u>		
						15. TOTAL	• 2	0	0	
G. PREPARED B	Y		H. DATE	I. APPROVE	D BY		J. DA	TE		
(b) (6)	( <u> </u>		∎│							
		1	- DDCV/	OUS EDITION MAY			40-6	22	D	
	23-1, FEB 200		FREVI		DE USED.	Page _	12 of Adol		Pages sional 8.0	

	CONTRACT I	DATA RI (1 Data		TS LIST		Form Appro OMB No. 07		38		
data sources, gatherin other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information idents should be aware th	ata needed, an n, including s at notwithsta valid OMB c	nd completing and re suggestions for redu anding any other pro control number. Plea	eviewing the collection of ucing the burden, to the vision of law, no person s ase do not return your for	information. Department hall be subject	the time for reviewing instr Send comments regarding the of Defense, Executive Servet to any penalty for failing to ve organization. Send complete	his burder ices Dire comply y	n estimat ctorate vith a co	te or any	
A. CONTRACT I	INE ITEM NO.	B. EXHIE	BIT	C. CATEGORY:						
0 D. SYSTEM/ITE	001		A E. CONTRACT			RACTOR				
	Therapeutics			QY21C0016	F. CONT	Lilly				
1. DATA ITEM NO.	2. TITLE OF DATA ITEN	n		-	3. SUBTITL	E				17. PRICE GROUP
A013	Pandemic Manage	ement Plan	ı 							
	Acquisition Document No -TCSP-82040	L)	5. CONTRACT RE	FERENCE		6. REQUIRING OFFICE	RDA			18. ESTIMATED TOTAL PRICE
7. DD 250 REQ	9. DIST STATEMENT	10. FREQU	ENCY	12. DATE OF FIRST SU	MISSION	14. DISTRIB				
	REQUIRED	see	remarks	see remar			b	. COPIES	s	
8. APP CODE		11. AS OF	DATE	13. DATE OF SUBSEQU SUBMISSION		a. ADDRESSEE	Draft	Fi	nal	
40.05040040				see remar	s	BARDA		Reg	Repro	
16. REMARKS A pandemic faci	ility and/or operation	nal manao	ement plan incl	uding change proced	ures from		1			
-		-	-	rational plan to conti		JFEO CBRIVD				
	e event of a declared			-						
	bmit Pandemic Mar	nagement l	Plan:							
Draft within 15     Final within 30	•									
							<u> </u>			
							<u> </u>			
							1			
	~		U. DATE			15. TOTAL	2	0	0	
G. PREPARED B	Ŷ		H. DATE	I. APPROVE	JBA		J. DA	1E		
(b) (6)	8		•	(b) (6)	j					
DD FORM 14	23-1, FEB 200	1	PREVIO	OUS EDITION MAY	BE USEĎ.	Page	13 of 3	32	Pages	11
							Adob	e Profes	sional 8.0	

	CONTRACT	DATA R (1 Data		ITS LIST		Form Appl OMB No.		88		or any
data sources, gatherin other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of informatio idents should be aware th	ata needed, a n, including s hat notwithsta y valid OMB o	nd completing and suggestions for red anding any other pro control number. Ple	reviewing the collection of lucing the burden, to the ovision of law, no person s ase do not return your for	information. Department hall be subject	g the time for reviewing in Send comments regarding of Defense, Executive Si tt to any penalty for failing ve organization. Send com	g this burder ervices Dire to comply y	n estima ctorate with a co	te or any	
A. CONTRACT I	LINE ITEM NO. 001	B. EXHIE		C. CATEGORY:	отн					ion
D. SYSTEM/ITE			A E. CONTRAC			RACTOR				
	Therapeutics		W911	QY21C0016		Lilly				
1. DATA ITEM NO.	2. TITLE OF DATA ITEM		Translation		3. SUBTITL	E				
A014	Supply Chain and	Distributi	on Tracking							
	Acquisition Document No -TCSP-82040	p.)	5. CONTRACT RE	FERENCE		6. REQUIRING OFFICE	ARDA			
7. DD 250 REQ	9. DIST STATEMENT	10. FREQU	ENCY	12. DATE OF FIRST SU	BMISSION					
77 00 200 HEL	REQUIRED		remarks	see remar				D. COPIE	s	
8. APP CODE		11. AS OF	DATE	13. DATE OF SUBSEQU SUBMISSION	ENT	a. ADDRESSEE	Draft	Fi	inal	
				see remar	ks			Reg	Repro	
16. REMARKS	acent of Operations	BARDA	and MCM Ma	mufacturers play an i	mortant	BARDA JPEO CBRND	1			
				e under a nationwide	-	JPEO CBRND	1			
	-			in the manufacturing	-		<u> </u>			
-	-	-		rdee will relay final o	-					
-	-			SPR for allocation an	-		_			
	-			returned to BARDA, n to ship therapeutics			_			
sites of administ		s will use		n to ship therapeuties	in our to		_			
Provide the follo	owing information i	n order to	coordinate the	movement and delive	ry of		<u> </u>			
-	nanufacturing locati									
			· · · ·	mail) for manufactu	-		_			
				e and distribution loo Distribution• Labeling			_			
	-			ormation as soon as			_			
	ninimum, include th		-				<u> </u>			
				ary container. Unit of						
				ional Drug Code (NE L)• Unit of Sale weig			_			
				ntermediate Package			_			
	-	-		bility Information • (	-		_			
	planned shipment p	-	-				<u> </u>			
-	-	-	-	the designated distri litate pick/pack proce						
	e of workers to ultra			ntate pick/pack proce	ss and		_			
-	lowing DSCSA dat	-		S in packing lists.			_			
	reement number on						_			
	of the MSDS (with	n QR code)	in the packing	list envelope with ea	ch					
shipment. • Send EDI 856	Advanced Shipmer	t Notice fo	or all products s	hipped to a USG dir	ected					
				related documents to			_			
	atching on the day s						_			
							_			
						15. TOTAL	→ 2	0	) 0	
G. PREPARED B	Y		H. DATE	I. APPROVE	D BY	-	J. DA	-		
	í <u> </u>		• I							
		4		(b) (6) OUS EDITION MAY				22	P	11
	23-1, FEB 200	1	FREVI		DE USED.	Page .	14 of Adob		Pages	

	CONTRACT I	DATA RI (1 Data		TS LIST		Form Appro OMB No. 0		88			
data sources, gatherir other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information idents should be aware th	ata needed, an n, including s nat notwithsta v valid OMB c	nd completing and re suggestions for redu anding any other pro- control number. Plea	eviewing the collection of ucing the burden, to the vision of law, no person sl use do not return your forr	information. Department hall be subject	g the time for reviewing inst Send comments regarding of Defense, Executive Ser t to any penalty for failing t ve organization. Send comp	this burder vices Dire to comply v	n estima ctorate with a c	te or any		
A. CONTRACT L	INE ITEM NO.	B. EXHIE	BIT	C. CATEGORY: TDP X TM							
0 D. SYSTEM/ITEM	001 vi		A E. CONTRACT			RACTOR					
-	Therapeutics			QY21C0016		Lilly					
1. DATA ITEM NO.	2. TITLE OF DATA ITEN	И			3. SUBTITL	E				17. PRICE	GROUP
A015	Distribution Plan										
	Acquisition Document No -TCSP-82040	p.)	5. CONTRACT REF	ERENCE		6. REQUIRING OFFICE	RDA			18. ESTIN TOTA	NATED
7. DD 250 REQ	9. DIST STATEMENT	10. FREQU	ENCY	12. DATE OF FIRST SU	MISSION	14. DISTRIE					
	REQUIRED	see	remarks	see remar			b	. Copie	s		
8. APP CODE		11. AS OF	DATE	13. DATE OF SUBSEQU SUBMISSION		a. ADDRESSEE	Draft		inal		
16. REMARKS				see remar	<u>s</u>	BARDA	1	Reg	Repro	1	
	lescribe the Awarde	e's proces	s to allocate (the	e global allocation m	odel) and		1				
-		-		ilities, necessary to 1	-						
				with applicable prov							
				585 of PL 113-54 (N							
	to account FDA's re	egular guid	lance for the CC	OVID-19 public heal	th					1	
response.											
- Within 7 days	of award										
-											
										1	
							_				
								<u> </u>			
								<u> </u>			
										Ì	
										1	
										1	
							_				
								-	+		
										1	
						15. TOTAL	• 2	(	) 0		
G. PREPARED B	Y		H. DATE	I. APPROVE	D BY		J. DA	TE			
(b) (6)	8			(b) (6)							
DD FORM 14	23-1, FEB 200	1	PREVIO	DUS EDITION MAY	BE USED	Page	15 of 3	30	Pages	1	
	20-1, FED 200	•				raye_			- ssional 8.0		

	CONTRACT	DATA R (1 Data		TS LIST		Form Appro OMB No. 03		88			
data sources, gatherir other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information dents should be aware th	ata needed, au n, including s hat notwithsta y valid OMB c	nd completing and r suggestions for red anding any other pro control number. Ple	eviewing the collection of ucing the burden, to the vision of law, no person s ase do not return your for	information. Department hall be subject	g the time for reviewing instr Send comments regarding t of Defense, Executive Servent t to any penalty for failing to ve organization. Send compl	this burden vices Dire comply v	n estimat ctorate with a co	te or any		
A. CONTRACT L	INE ITEM NO. 001	B. EXHIE	BIT A	C. CATEGORY: TDP X TM	отн	ER	BARDA				
D. SYSTEM/ITEM	Λ		E. CONTRACT	Г/PR NO.		RACTOR					
1. DATA ITEM NO.	Therapeutics 2. TITLE OF DATA ITEN	и	W911	QY21C0016	3. SUBTITL	Lilly				17. PF	ICE GROUP
A016	Manufacturing De		t Plan			_	BARDA DISTRIBUTION GEE Draft Reg				
	Acquisition Document No -TCSP-82040	p.)	5. CONTRACT RE	FERENCE SOW	-	6. REQUIRING OFFICE	RDA				TIMATED
7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQU		12. DATE OF FIRST SU	BMISSION	14. DISTRIB	UTION				
0. ADD 00D5	nedonieb		e remarks	see remar			t	-			
8. APP CODE		11. AS OF	DATE	SUBMISSION see remar		a. ADDRESSEE	Draft		nal Repro		
16. REMARKS		•		•		BARDA	1				
				for the drug/biologic		JPEO CBRND					
		· · ·		nd Cosmetics Act (F good manufacturing							
				tance studies; list of					i		
	-	-	-	appropriate, shall be	-						
			-	summary from initia	-						
-				es; manufacturing p							
-	l validation program pice, rationale]; mic			osure system docum	ents						
	-	-		ent and validation, s	tability						
plan; and any as		ipitation),	assay developin	ent and vandation, s	laonity						
1 , ,	,										
• Plan will be de	livered electronical	ly within 3	0 days of Agre	ement award to the A	O and						
AOR											
									i i		
									<b> </b>		
								<u> </u>			
									┼─┨		
						15. TOTAL	2	0	0		
G. PREPARED B	Y		H. DATE	I. APPROVE	D BY		J. DA	TE			
(b) (6)	4		•	(b) (6)			40 - 6	20			
DD FORM 14	23-1, FEB 200	1	PREVI	OUS EDITION MAY	BE USED.	Page	16 of Adol		Pages sional 8.0		

	CONTRACT	DATA R (1 Data		ITS LIST		Form Appr OMB No. (		88			
data sources, gatherin other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information	ata needed, a n, including s nat notwithsta v valid OMB c	nd completing and suggestions for rea anding any other pr control number. Pla	reviewing the collection of lucing the burden, to the ovision of law, no person ase do not return your for	f information. Department	g the time for reviewing ins Send comments regarding of Defense, Executive Se to any penalty for failing ve organization. Send com	this burder	n estimat ctorate	te or any		
A. CONTRACT I	-	B. EXHIE		C. CATEGORY: TDP X TM	отн	FR					
D. SYSTEM/ITE			E. CONTRAC			RACTOR					
1. DATA ITEM NO.	Therapeutics 2. TITLE OF DATA ITEN	a	W911	QY21C0016	3. SUBTITL	Lilly				17. P	RICE GROUP
A017	Quality Managem				3. 808111	L.					
	Acquisition Document No -TCSP-82040	). <b>)</b>	5. CONTRACT RE	FERENCE		6. REQUIRING OFFICE	RDA				STIMATED
7. DD 250 REQ	9. DIST STATEMENT	10. FREQU	ENCY	12. DATE OF FIRST SU	BMISSION		IBUTION				
	REQUIRED		remarks	see remai			b	. Copies			
8. APP CODE		11. AS OF	DATE	SUBMISSION SUBMISSION		a. ADDRESSEE	Draft	Fi Reg	nal Repro		
16. REMARKS	1	1		_		BARDA	1				
		-		objectives, managen		JPEO CBRND	1				
-				, feedback, evaluation t, measurement, and			_		┼──┨		
				nfrastructure, senior						Ì	
			-	management, and qu							
management sys	stem evaluation										
	livered electronical	ly within 1	4 days of Agre	ement award to the	AO and						
AOR											
										1	
							_				
							_				
							_				
							_				
										1	
							_	<u> </u>			
							_	<u> </u>	┼──┨		
						15. TOTAL	▶ 2	0	0		
G. PREPARED B	Y		H. DATE	I. APPROVE	D BY	•	J. DA	-			
(h) (6)	<u>,</u>										
	23-1, FEB 200	1	PDEV/	OUS EDITION MAY	BE LISED	Deer	17 of 3	32	Pages		
	23-1, FED 200	•		COULDITION WAT	DE UGED.	Page _			Pages sional 8.0		

	CONTRACT I	DATA RI (1 Data		TS LIST		Form Appro OMB No. 0		88		
data sources, gatherin other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information idents should be aware th	ta needed, and n, including s at notwithsta valid OMB c	nd completing and re suggestions for redu anding any other pro control number. Plea	eviewing the collection of ucing the burden, to the vision of law, no person sl ase do not return your forr	information. Department hall be subject	g the time for reviewing inst Send comments regarding of Defense, Executive Ser ct to any penalty for failing t ve organization. Send comp	this burder vices Dire o comply v	Directorate Directorate mply with a collection	e or any	
A. CONTRACT L		B. EXHIE		C. CATEGORY:			completed form to the			
0 D. SYSTEM/ITE	001		A E. CONTRACT							
-	Therapeutics			QY21C0016	1.000	Lilly				
1. DATA ITEM NO.	2. TITLE OF DATA ITEN	1		-	3. SUBTITL	E				17. PRICE GROUP
A018	Quality Agreemen	ıt								
	Acquisition Document No or format acceptat		5. CONTRACT RE	FERENCE		6. REQUIRING OFFICE	RDA			18. ESTIMATED TOTAL PRICE
7. DD 250 REQ	9. DIST STATEMENT	10. FREQU	ENCY	12. DATE OF FIRST SUI	MISSION	14. DISTRIE				
	REQUIRED	see	remarks	see remar			b	. Copies	6	
8. APP CODE		11. AS OF	DATE	13. DATE OF SUBSEQU SUBMISSION		a. ADDRESSEE	Draft	Fir		
16. REMARKS				see remar	ζS	BARDA	1	Reg	Repro	
	determine the condi	tions of ac	ceptance by the	USG of the purchas	ed	JPEO CBRND	1			
-				ity agreement is in pl						
	be signed by the US	G and the	manufacturer v	vithin 14 days of Ag	reement					
award										
<ul> <li>Agreement will</li> </ul>	ll be delivered electr	onically to	o the AO and A	OR						
										•
										-
								<u> </u>		
						15. TOTAL	• 2	0	0	
G. PREPARED B	Y		H. DATE	I. APPROVE	) BY		J. DA	TE		
(b) (6)	<u>,                                     </u>									
		1		(D) (6) DUS EDITION MAY			18 of	32	Dee	
	23-1, FEB 200		PREVIC		DE USED.	Page _			Pages	

Adobe Professional 8.0

					livery	ompliance cticable, prior to de	Certificate of Co • as soon as prac
	1	JPEO CBRND				-	Certificate of Ar
Draft Reg Repro	_	BARDA	submission see remarks				16. REMARKS
b. COPIES Final	b	a. ADDRESSEE	see remarks 13. DATE OF SUBSEQUENT	remarks	See	-	8. APP CODE
			SOW 12. DATE OF FIRST SUBMISSION	ENCY	10. FREQU	or format acceptal 9. DIST STATEMENT REQUIRED	7. DD 250 REQ
18. ESTIMATED TOTAL PRICE		6. REQUIRING OFFICE		5. CONTRACT REF		Acquisition Document No	
				oses to be deliv		Release document	A019
17. PRICE GROUP		Lilly	IQY21C0016 3. SUBTIT	W9110	м	Therapeutics 2. TITLE OF DATA ITER	1. DATA ITEM NO.
i		IER	Т/PR NO. F. CONT	A E. CONTRACT		001 <b>v</b>	0 D. SYSTEM/ITEM
	·		C. CATEGORY:	No. listed in Block E. SIT	B. EXHIE	Contracting Officer for the LINE ITEM NO.	Government Issuing C A. CONTRACT L
his burden estimate or any vices. Directorate	g this burden ervices Direc	Send comments regarding t of Defense Executive Sen	verage 110 hours per response, includin reviewing the collection of information. ducing the burden, to the Department ovision of law, no person shall be subje ease do not return your form to the abo	nd completing and re suggestions for redu nding any other prov ontrol number. Plea	ata needed, a n, including s hat notwithsta y valid OMB c	ng and maintaining the da collection of informatio indents should be aware th bes not display a currently	data sources, gatherin other aspect of this (0704-0188). Respon of information if it do
		Form Appro OMB No. 0			DATA R	CONTRACT	

					J.	(b) (6)	<u> </u>		P	
									X	(b) (6)
		TE	J. DA		D BY	I. APPROVE	H. DATE		Y	G. PREPARED B
0	0	0	2	15. TOTAL						
41										
41										
-11			<u> </u>							
-11	<b>—</b>		<u> </u>							
-11			<u> </u>							
-11			<u> </u>							
-11			<u> </u>							
-1										
-11										
-di										
-1			<u> </u>							
-1 i			<u> </u>							
-41			<u> </u>							
-1 i			<u> </u>							
-11			<u> </u>							
<b>-1</b> 1										
4			<u> </u>							
<b>1</b> ;										
1										
1										
1										
1										
1										
<b>1</b> ¦										
<b>1</b> ¦										
1										
1!										
-										
1										
1						r				
-11			<u> </u>		deliverv	cated prior to dose d	mments adjudi	JSG and co	to be reviewed by U	Documentation
<b>-1</b> 1			<u> </u>							an a dimery findin
-11					Servereu	and product will be	substance and 0	ar tor drug	-	in a timely man
<b>-1</b> ;				JELO CDINID	-	rug product will be				
1			1	JPEO CBRND	a sample	ompliance; and (3) a	onformance/Co	ificate of (	f Analysis: (2) Certi	
1	-	-	1	BARDA					1	16. REMARKS
1	Repro	Reg	Draft		rks	SUBMISSION see remar				
	al	Fin	D (	a. ADDRESSEE	UENT	13. DATE OF SUBSEQU SUBMISSION	DATE	11. AS OF	1	8. APP CODE
		. Copies	b			see remar	remarks	see	NEQUIKED	
			JTION	14. DISTRIBU	JBMISSION	12. DATE OF FIRST SU		10. FREQU	9. DIST STATEMENT REQUIRED	7. DD 250 REQ
TOTAL PRICE			DA	BAR		SOW		ble	or format acceptat	contracto
18. ESTIMATED				6. REQUIRING OFFICE			5. CONTRACT RE		Acquisition Document No	
									, and the second s	A020
					1		ion Records		Manufacturing and	
17. PRICE GROUP				-	3. SUBTITL	<b>_</b>		vi	2. TITLE OF DATA ITEN	1. DATA ITEM NO.
I!				Lilly		QY21C0016			Therapeutics	
-1				RACTOR			E. CONTRACT	<u> </u>		D. SYSTEM/ITE
				IER	отн		A		0001	
<b>-1</b> 1						C. CATEGORY:		B. EXHII	Contracting Officer for the	A. CONTRACT L
	ection	to the	comply v eted form	ct to any penalty for failing to ve organization. Send comple	shall be subjec rm to the abov	ise do not return your for	ontrol number. Plea	y valid OMB o	pes not display a currently	of information if it do
	e or any	estimate	nis burder ices Dire	Send comments regarding th of Defense, Executive Servi	f information. e Department	eviewing the collection of ucing the burden, to the	nd completing and re suggestions for redu	ata needed, a n, including :	ng and maintaining the da collection of information	data sources, gatherin other aspect of this
3	existing	arding this burden estimate ve Services Directorate ailing to comply with a colle	g the time for reviewing instru	onse, including	erage 110 hours per respo	n is estimated to ave	of informatio	burden for this collection	The public reporting t	
		38		OMB No. 07				(1 Data		
			ved	Form Approv		TS LIST	EQUIREMEN	DATA R	CONTRACT I	

	CONTRACT	DATA R (1 Data			Form Appro OMB No. C					
data sources, gatherir other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information dents should be aware th	ata needed, a n, including s nat notwithsta valid OMB c	nd completing and i suggestions for red anding any other pro ontrol number. Ple	reviewing the collection of ucing the burden, to the ovision of law, no person s ase do not return your for	information. Department shall be subject	g the time for reviewing ins Send comments regarding of Defense, Executive Set t to any penalty for failing we organization. Send com	this burder rvices Dire to comply v	n estima ctorate with a co	te or any	
A. CONTRACT L	INE ITEM NO. 001	B. EXHIE	BIT A	C. CATEGORY: TDP X TM	отн	ER				
D. SYSTEM/ITEM	VI N		E. CONTRAC	T/PR NO.		RACTOR				
1. DATA ITEM NO.	Therapeutics 2. TITLE OF DATA ITEN	4	W911	3. SUBTITI	Lilly F	17. PRICE GROUP				
A021	Security Plan					-				
	Acquisition Document No or format acceptal		5. CONTRACT RE	FERENCE		6. REQUIRING OFFICE	RDA			18. ESTIMATED TOTAL PRICE
7. DD 250 REQ	9. DIST STATEMENT	10. FREQU	ENCY	12. DATE OF FIRST SU	BMISSION		BUTION			
	REQUIRED	see	remarks	see remar			t	. COPIE	s	
8. APP CODE		11. AS OF	DATE	13. DATE OF SUBSEQU SUBMISSION See remar		a. ADDRESSEE	Draft	Fi Reg	nal Repro	
16. REMARKS				See Tellian	A.S	BARDA	1	nog	liopio	
				rall protection of per		JPEO CBRND	1			
				Government requires nonstrate how the Av				<u> </u>		
-	lhere to the security	-			wardee					
	-	-		ered to the Governm	ent within					
				e commercially reas						
				e. performing work o						
	mply with all Gover idee will flow-down			ents and Awardee se	curity					
-	contracts executed	-		•			_			
-	contracts executed									
	-		-	ent; provided that in						
	-			ons to any sub-awar						
				e Awardee will have ct these flow-down	e a period					
	-			ardee's material con	pliance					
-	ow-down requireme				1					
The Government	t will review in deta	ail and sub	mit comments	within ten (10) busin	ess days					
to the Agreemen	ts Officer (AO) to l	be forward	ed to the Awar	dee. The Awardee sh						
	ty Plan comments, a			•						
	hin thirty (30) caler	-	-							
	ed by the Governme		compliance of a	all the required secur	ny					
incustares outline							_			
				rdee shall supply to t			_			
~	icer a letter certifyi	ng complia	nce to the elem	ents outlined in the	Final					
Security Plan.										
							_			
							_	<b> </b>		
						15. TOTAL	• 2	0	0	
G. PREPARED B	Y		H. DATE	I. APPROVE	D BY		J. DA		U U	
(b) (6)	À			(b) (6)						
DD FORM 14	23-1, FEB 200	1	PREVI	OUS EDITION MAY	BE USED.	Page _	21 of Adot		Pages sional 8.0	

	CONTRACT		Form Approved OMB No. 0704-0188								
data sources, gatherir other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of informatior idents should be aware th bes not display a currently	ta needed, an n, including s at notwithsta valid OMB c	nd completing and r suggestions for red inding any other pro ontrol number. Ple	information. Department hall be subject	the time for reviewing instr Send comments regarding ti of Defense, Executive Serv t to any penalty for failing to ve organization. Send compl	his burder rices Director comply v	n estimate ctorate vith a col	e or any			
A. CONTRACT L	Contracting Officer for the LINE ITEM NO.	B. EXHIE		C. CATEGORY:							
_	001		A							1	
D. SYSTEM/ITEM	M Therapeutics		E. CONTRAC W011	Г/PR NO. QY21C0016	F. CONT	DNTRACTOR Lilly					
1. DATA ITEM NO.	2. TITLE OF DATA ITEN	1	won	Q12100010	3. SUBTITL	-				1	7. PRICE GROUP
A022	Supply Chain Res	iliency Pla	n								
	Acquisition Document No MGMT-81808	.)	5. CONTRACT RE	FERENCE SOW		6. REQUIRING OFFICE	RDA			1	8. ESTIMATED TOTAL PRICE
7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQU		12. DATE OF FIRST SU		14. DISTRIB					
8. APP CODE	-	11. AS OF	remarks	see remar		a. ADDRESSEE	b	. COPIES Fin		Ľ	
6. AFF CODE		11. A5 OF	DATE	SUBMISSION see remar	cs	a. ADDRESSEE	Draft	Reg	Repro		
16. REMARKS						BARDA	1		-		
A comprehensiv	ve Supply Chain Res	iliency Pro	ogram that prov	vides identification a	nd	JPEO CBRND	1				
	-			pply of drug substan	ce, drug						
	rk-in-process throug										
-		-		al to the product or the	ne						
		-		in the definition are						1	
	cility and capital equ		manufacturing.	NOT included in the							
		-	the evaluation	and potential impact	ofraw					L	
	-			arts, software, firmw							
-	-			ponentry, reagents, o							
materials which	are used in the man	ufacturing	of a drug, cell	banks, seed stocks, d	evices					1	
	ing components and										
A clear example	e of a critical compo	nent is one	where a sole s	upplier is utilized.							
				locations, local resou							
	-			cument shall address m, downstream, com			<b></b>				
-	-	-	-	sary for the delivery	-						
product.										1	
a) Communicati	on for these require rt of regular contrac			part of an annual rev	view, or as						
• • • •	-			and re-usable in-plac	e		<b></b>				
· -	-		-	all be addressed. For							
goods, the inspe	ction, labeling, pack	aging, and		chinery shall be add							
<u> </u>	unt capacity capabil										
· ·	•	•		omponents and aspec							
	-	-	-	nethods shall be addr volume, which wou							
	-		-	ally agreed deliverie						1	
Significantly and	eet an oughput and t			any agreed deniverie							
The Awardee sh	all articulate in the	plan, the m	nethodology for	inventory control, p	roduction		<u> </u>			Ì	
				part of those agreed							
a) Production rat	tes and lead times sl	hall be und	lerstood and co	mmunicated to the (c	ontinued)						
				1							
										י ו	
	<u>, , , , , , , , , , , , , , , , , , , </u>		UL DATE			15. TOTAL	2	0	0		
G. PREPARED B	Y		H. DATE	I. APPROVE	JBA		J. DA	IE			
(b) (6)	).			(b) (6)	,						
DD FORM 14	23-1, FEB 200	1	PREVI	OUS EDITION MAY	BE USED.	Page	22 of	32	Pages	I	

Adobe Professional 8.0

CONTRACT DATA REQUIREMENTS LIST (1 Data Item)								
A. CONTRACT LINE ITEM NO. 0001	B. EXHIBI	т А	C. CATEGORY: TDP X TN					
D. SYSTEM/ITEM Therapeutics	E F	E. CONTRACT W9110	r/pr no. QY21C0016	F. CONTRACTOR Lilly				
<ul> <li>16. REMARKS (Continued)</li> <li>Agreements Officer or the Agreeme</li> <li>b) Production throughput critical condesign, and communicated to contrasecondary constraints of throughput</li> <li>Reports for critical items should incl.</li> <li>I. Critical Material</li> <li>II. Vendor</li> <li>III. Supplier, Manufacturing / Distri</li> <li>IV. Supplier Lead Time</li> <li>V. Shelf Life</li> <li>VI. Transportation / Shipping restrict</li> <li>The AO and AOR reserve the right performance, for distribution within</li> </ul>	nstraints sho actual person , as appropri- lude the foll bution Loca ctions to request ur the Governm the Governm ten (10) day	s Representativ ould be well un nnel. As necess riate. lowing informa ation an-redacted cop ment. ays after AO iss e Limited Righ	ve as necessary. nderstood by activit sary, communication ation: pies of technical doorsues the request. Th	vity and by ion should focus on identification, exploitation, elevation, and ocuments provided in response to this subsection, during the period of The contractor may arrange for additional time if deemed necessary, and				

	CONTRACT	DATA R (1 Data			Form Approved OMB No. 0704-0188					
data sources, gatherir other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information dents should be aware th	ata needed, a n, including s hat notwithsta y valid OMB c	nd completing and suggestions for rea anding any other pr control number. Pla	reviewing the collection of ducing the burden, to the ovision of law, no person s ease do not return your for	information. Department hall be subject	g the time for reviewing im Send comments regarding of Defense, Executive Se t to any penalty for failing ve organization. Send com	g this burde ervices Dire to comply 1	n estimat ctorate with a co	te or any	
A. CONTRACT L	INE ITEM NO. 001	B. EXHIE	BIT A	C. CATEGORY: TDP X TM	отн	IED				
D. SYSTEM/ITEM			E. CONTRAC		RACTOR					
	Therapeutics		W911	QY21C0016		Lilly				17. PRICE GROUP
1. DATA ITEM NO. A023	2. TITLE OF DATA ITEM Manufacturing Da		ements		3. SUBTITL	E				
	Acquisition Document No MGMT-81808	o.)	5. CONTRACT R	FERENCE		6. REQUIRING OFFICE	ARDA			18. ESTIMATED TOTAL PRICE
7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQU		12. DATE OF FIRST SU	BMISSION	14. DISTR	RIBUTION			
	REQUIRED		remarks	see remat		-	t	D. COPIES		
8. APP CODE		11. AS OF	DATE	SUBMISSION SUBMISSION		a. ADDRESSEE	Draft	Fir	nal Repro	
16. REMARKS				see remai	KS	BARDA	1	neg	періо	
				facturing sites, inclue	-	JPEO CBRND	1			
-	-		-	essed material by type						
	n and nature of wor and location and nat			uring, processing, an	d		_			
mi/misii sices, a	and location and hat			linear studies sites.						
• Within 30 cale	ndar days of award									
				Awardee to be used t						
		ial develop	ment, which w	ould include but not	be limited					
to the following:	: itory of ancillary ma	aterials (vi	als needles sv	ringes etc.)			_			
	ancillary materials (	-	-							
	ncillary materials (v									
	ment or other startin	-		g						
	ostance and/or adjuv	-								
	nd release of produc			filled/final product of	r adjuvant					
	mation of bulk sub				n aujuvani					
	oulk substance of fi									
10) Disposal of	bulk substance or fi	nal materi	al							
							_			
								<b> </b>		
								$\vdash$		
						15. TOTAL	→ 2	0	0	
G. PREPARED B	Y		H. DATE	I. APPROVE	D BY	-	J. DA			
(b) $(c)$										
		4		(b) (6) IOUS EDITION MAY	DE LIGER		24-5	22		
UU FUKIM 14	23-1, FEB 200		PREV	IOUS EDITION MAY	DE USED.	Page -	24 of Adol		Pages sional 8.0	

	CONTRACT	DATA R (1 Data		Form Approved OMB No. 0704-0188						
data sources, gatherin other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information idents should be aware th	ata needed, an n, including s nat notwithsta v valid OMB c	nd completing and i suggestions for red anding any other pro ontrol number. Ple	reviewing the collection of ucing the burden, to the ovision of law, no person s ase do not return your for	information. Department hall be subject	g the time for reviewing instr Send comments regarding t of Defense, Executive Serv t to any penalty for failing to ve organization. Send compl	his burder rices Dire comply v	n estima ctorate vith a co	te or any	
A. CONTRACT I	-	B. EXHIE		C. CATEGORY: TDP X TM	отн	50				
D. SYSTEM/ITE			E. CONTRAC			RACTOR				
	Therapeutics		W911	QY21C0016		Lilly				
1. DATA ITEM NO.	2. TITLE OF DATA ITEN	л			3. SUBTITL	E				17. PRICE GROUP
A024	BARDA Audit									
	Acquisition Document No [-SESS-81921	<b>).</b> ]	5. CONTRACT RE	ference SOW		6. REQUIRING OFFICE	RDA			18. ESTIMATED TOTAL PRICE
7. DD 250 REQ	9. DIST STATEMENT	10. FREQU	ENCY	12. DATE OF FIRST SU	BMISSION	14. DISTRIB				
	REQUIRED		remarks	see remar			b	. Copie		
8. APP CODE		11. AS OF	DATE	13. DATE OF SUBSEQU SUBMISSION See remar		a. ADDRESSEE	Draft	Fi Reg	Repro	
16. REMARKS				see reman	K.5	BARDA	1	neg	nepro	
	-			y BARDA. If BARD	-	JPEO CBRND	1			
	-	•	-	lit, the contractor sha	-					
				BARDA • If issues BARDA detailing th						
	ction(s) within 10 b		-	Different detailing a	ie midnig					
• AOR and AO				to the Contractor wi	th 10					
business days		1.1.4	1 '11							
Once correctiv	e action is complete	ed, the Awa	ardee will prov	ide a final report to I	SARDA					
						15. TOTAL	2	0	) 0	
G. PREPARED B	Y		H. DATE	I. APPROVE	D BY		J. DA	TE		
(b) (6)	2		•	(b) (6)			1			
DD FORM 14	23-1, FEB 200	1	PREVI	OUS EDITION MAY	BE USEĎ.	Page	25 of	32	Pages	
							Adob	e Profes	sional 8.0	

	CONTRACT	DATA R (1 Data			Form Approved OMB No. 0704-0188					
data sources, gatherir other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information idents should be aware th	ta needed, a n, including s at notwithsta valid OMB c	nd completing and re suggestions for redu anding any other pro control number. Plea	eviewing the collection of ucing the burden, to the vision of law, no person s ase do not return your for	information. Department hall be subject	the time for reviewing inst Send comments regarding of Defense, Executive Ser t to any penalty for failing t ve organization. Send comp	this burder vices Dire o comply v	n estima ctorate with a c	te or any	
A. CONTRACT L	_	B. EXHIE		C. CATEGORY:	отн	ED				
D. SYSTEM/ITEM			E. CONTRACT			RACTOR				
	Therapeutics		W911	QY21C0016		Lilly	17. PRICE GROUP			
1. DATA ITEM NO. A025	2. TITLE OF DATA ITEN FDA Inspections	1			3. SUBTITL	E				17. PRICE GROOP
	Acquisition Document No [-SESS-81921	J	5. CONTRACT RE	FERENCE	•	6. REQUIRING OFFICE	RDA			18. ESTIMATED TOTAL PRICE
7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQU		12. DATE OF FIRST SU	-		BUTION			
8. APP CODE		See 11. AS OF	remarks	see remar		a. ADDRESSEE		. COPIE	S	<b> </b>
				SUBMISSION see remar	ks		Draft	Reg	Repro	
16. REMARKS	n FDA inspection th	at occurs	in relation to th	is contract and for th	e product	BARDA JPEO CBRND	1			
	-			tial to impact the pe	-		1			• 
of this contract,	the Awardee shall p	rovide the	USG with an e	xact copy (non-reda	cted) of					
		-		EIR). The Awardee						
-	-	-		ng areas of non-cont ntified in the audit re						
				al responses to the F						
		-		red from subawardee						
		_		actor shall make arra	-					
for BARDA repr inspector	resentative(s) to be	present du	ring the final de	brief by the regulate	ory					
mspector										
Contractor shall	ll notify AO and AO	OR within	10 business day	rs of a scheduled FD	A audit or					
				ot provide advanced						
				eived from subaward usiness day of receiv						
	from the FDA or the	-		usiness day of receiv	шg					
			ractor shall pro	vide AO with a plan	for					
addressing areas	s of nonconformance	e, if any ar	e identified							
								<u> </u>		
										•
								<u> </u>		
0.0000000000000000000000000000000000000					0.011	15. TOTAL	2	(	) 0	-
G. PREPARED B	Ŷ		H. DATE	I. APPROVE	DBY		J. DA	TE		I
(b) (6)	8			(b) (6)	)		ı			
DD FORM 14	23-1, FEB 200	1	PREVIO	OUS EDITION MAY	BE USED.	Page _	26 of	32	Pages	I

Adobe Professional 8.0

	CONTRACT	DATA R (1 Data			Form Approved OMB No. 0704-0188					
data sources, gatherin other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information idents should be aware th	ata needed, a n, including s nat notwithsta valid OMB c	nd completing and a suggestions for red anding any other pro ontrol number. Ple	reviewing the collection of lucing the burden, to the ovision of law, no person s ase do not return your for	information. Department hall be subject	g the time for reviewing ins Send comments regarding of Defense, Executive Se at to any penalty for failing to ve organization. Send comp	this burder rvices Dire to comply v	n estima ctorate vith a co	te or any	
A. CONTRACT I	_	B. EXHIE		C. CATEGORY: TDP X TM	отн	FR				
D. SYSTEM/ITE	N		E. CONTRAC	T/PR NO.		RACTOR				
1. DATA ITEM NO.	Therapeutics 2. TITLE OF DATA ITEN	4	W911	QY21C0016	3. SUBTITL	Lilly F				17. PRICE GROUP
A026	QA Audits				0,000,000	-				
	Acquisition Document No -SESS-81921	p.)	5. CONTRACT RE	FERENCE		6. REQUIRING OFFICE	RDA			18. ESTIMATED TOTAL PRICE
7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQU	ENCY	12. DATE OF FIRST SU	BMISSION	14. DISTRI	BUTION			
	REQUIRED		remarks	see remar						
8. APP CODE		11. AS OF	DATE	SUBMISSION See remark		a. ADDRESSEE	Draft	Fi Reg	nal Repro	
16. REMARKS				•		BARDA	1			
			-	ned by the contractor	-	JPEO CBRND	1			
-			-	a report capturing the action is requested of	-				+	
subawardee, det	ailed concerns for a	ddressing	areas of non-co	nformance to FDA r	egulations					
	-			report, must be provi						
	ontractor shall provi ans for corrective ac	-	ses from the sul	pawardees to address	these					
							_			
	•		num of 10 busi	ness days in advance	of					
	s/site visits of subay		hin 5 husiness	days of report compl	tion					
	-			to the contractor wit						
business days	1		1							
							_			
							_			
										1
							_			
										1
							_	<u> </u>		
							_			
									+	
						15. TOTAL	2	0	0	
G. PREPARED B	Y		H. DATE	I. APPROVE	D BY	•	J. DA	_	, v	
$(\mathbf{b})$ $(\mathbf{c})$	,									
	23-1, FEB 200	1	- DDE//I	OUS EDITION MAY	RE LISED	Degr		30	Pages	
DD FURIVI 14	23-1, FEB 200	•	FNEVI		DE USED.	Page _	27 of Adot		Pages sional 8.0	

	CONTRACT	DATA R (1 Data		Form Approved OMB No. 0704-0188						
data sources, gatherir other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information dents should be aware th	ata needed, and n, including s nat notwithsta r valid OMB c	nd completing and suggestions for red anding any other pro ontrol number. Ple	reviewing the collection of lucing the burden, to the ovision of law, no person sl ase do not return your forr	information. Department nall be subject	g the time for reviewing instr Send comments regarding the of Defense, Executive Servent to any penalty for failing to we organization. Send completed	ices Dire comply v	n estimat ctorate vith a col	e or any	
A. CONTRACT L	INE ITEM NO. 001	B. EXHIE	A A	C. CATEGORY:	отн	Regulatory docu	uments			
D. SYSTEM/ITEM			E. CONTRAC	T/PR NO.		RACTOR				
1. DATA ITEM NO.	Therapeutics 2. TITLE OF DATA ITEN	1	W911	QY21C0016	3. SUBTITL	Lilly E				17. PRICE GROUP
A027	FDA Submissions									
	Acquisition Document No -TCSP-82040	.)	5. CONTRACT RE	FERENCE		6. REQUIRING OFFICE	RDA			18. ESTIMATED TOTAL PRICE
7. DD 250 REQ	9. DIST STATEMENT	10. FREQU	ENCY	12. DATE OF FIRST SU	MISSION	14. DISTRIBU				
	REQUIRED	see	remarks	see remark			b	. COPIES	;	
8. APP CODE		11. AS OF	DATE	13. DATE OF SUBSEQU SUBMISSION		a. ADDRESSEE	Draft	Fir	-	
16. REMARKS				see remar	<u>cs</u>	BARDA	1	Reg	Repro	
	hall provide BARD.	A the oppo	ortunity to revie	ew and comment upo	n all draft		1			
	-		•	provide BARDA with						
electronic copy "Draft" or "Fina		omission.	All documents	shall be duly marked	as either					
21010 01 1100	-									
				at least 15 business dee request and appro						
the AOR	ion of within a shor	ter timena	ine upon Awar	dee request and appro						
-				ness days of receipt o	r within a					
	ne upon Awardee red	-								
	must address, in wr FDA submission	riting, its c	onsideration of	all concerns raised b	У					
-		ubmitted to	BARDA conc	urrently or no later th	an 1					
calendar day of				,						
						45 7074	-	-		
G. PREPARED B	Y		H. DATE	I. APPROVE	) BY	15. TOTAL	2 J. DA	0 TE	0	
S. THE ARED D							0. DA			
(b) (6)	<u>A</u>			(b) (6)						
DD FORM 14	23-1, FEB 200	1	PREVI	OUS EDITION MAY	BE USED.	Page	28 of Adob	32 e Profess	Pages sional 8.0	

(D) (6) DD FORM 14	23-1, FEB 200	1	PREVI	(b) (6) OUS EDITION MAY	BE USEĎ.	Page	29 of	32	Pages		
										1	
G. PREPARED B	Y		H. DATE	I. APPROVE	) BY		J. DA	-	v		
1						15. TOTAL	2	0	0	1	
1							1				
							1				
							1			1	
							1				
							+				
									<u> </u>	I	
										1	
										1	
							<b> </b>			1	
										1	
							1				
1							1			1	
							1				
										1	
							1				
										1	
										1	
										1	
,							1				
• Upon award											
The rewardee SI	an provide a copy o	r any requ	STIDI DUA SU	oninted to the FDA		JPEO CBRIND					
	all provide a copy o	of any requ	est for EUA su	bmitted to the FDA		JPEO CBRND	1				
16. REMARKS	I	I		see remar	15	BARDA	1	Reg	Repro	1	
8. APP CODE		11. AS OF	DATE	SUBMISSION		a. ADDRESSEE	Draft	Fin			
9 400 0005	4			see remar				. COPIES		' <b>I</b>	
7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQU	ency remarks	12. DATE OF FIRST SU		14. DISTRIB					
	or format acceptat			SOW		BAF				I TOTAL PRICE	
	Acquisition Document No		5. CONTRACT RE			6. REQUIRING OFFICE				18. ESTIMATED TOTAL PRICE	
A028	Ũ										
A028	EUA filing										
1. DATA ITEM NO.	2. TITLE OF DATA ITEN	л			3. SUBTITL		17. PRICE GROUP				
	v Therapeutics			QY21C0016	F. CONT	Lilly					
D. SYSTEM/ITEM		1	E. CONTRACT		F. CONT						
A. CONTRACT L	LINE ITEM NO. 001	B. EXHIE	A A	C. CATEGORY: TDP TM	отн	Regulatory docu	uments				
Government Issuing C	Contracting Officer for the	Contract/PR	No. listed in Block E								
(0704-0188). Respon of information if it do	idents should be aware th bes not display a currently	at notwithsta valid OMB c	nding any other pro ontrol number. Plea	vision of law, no person sl ase do not return your forr	hall be subject	t to any penalty for failing to ve organization. Send compl	comply v eted form	vith a col to the	lection		
data sources, gatherin	ng and maintaining the da	ata needed, ar	nd completing and r	eviewing the collection of	information.	the time for reviewing instr Send comments regarding to of Defense, Executive Server	his burder	n estimate	existing e or any	1	
-		-	-								
	CONTRACT	DATA RI (1 Data		TS LIST		Form Appro OMB No. 07		28			

	CONTRACT	DATA RI (1 Data			Form Approved OMB No. 0704-0188						
data sources, gatherin other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information dents should be aware th	ata needed, ar n, including s hat notwithsta y valid OMB c	nd completing and re suggestions for redu anding any other pro control number. Plea	eviewing the collection of ucing the burden, to the vision of law, no person sl ase do not return your forr	information. Department hall be subject	g the time for reviewing inst Send comments regarding of Defense, Executive Ser t to any penalty for failing t ve organization. Send comp	this burder vices Dire cocomply v	n estima ctorate vith a co	te or any		
A. CONTRACT I	-	B. EXHIE		C. CATEGORY: TDP TM	отн	Regulatory doc	uments				
D. SYSTEM/ITE			E. CONTRACT		F. CONT	RACTOR					
1. DATA ITEM NO.	Therapeutics 2. TITLE OF DATA ITEM	vi	w911	QY21C0016	3. SUBTITL	E				17. PRICE GRO	OUP
A029	Provision of Publi	ie Law 115	5-92 Sponsor Au	uthorization Letter							
	Acquisition Document No -TCSP-82040	D.)	5. CONTRACT REP	FERENCE		6. REQUIRING OFFICE	RDA			18. ESTIMATE TOTAL PR	
7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQU		12. DATE OF FIRST SU	BMISSION	14. DISTRI	BUTION				
8. APP CODE		see	remarks	see remar		a. ADDRESSEE	b	. COPIE	S nal		
8. APP CODE		11. AS OF	DATE	SUBMISSION see remar		a. ADDRESSEE	Draft	Reg	Repro		
16. REMARKS				•		BARDA	1				
	all submit Public L mat that will be deli		-	rization Letter in the		JPEO CBRND	1				
Contractor s for	mat that will be den	ivered to th	ie designated O	w5100(3).							
• Within 30 days	s of award										
							-				
						15. TOTAL	• 2	0	0		
G. PREPARED B	Y		H. DATE	I. APPROVE	D BY		J. DA	TE			
(b) (6)	8		•	(b) (6)							
DD FORM 14	23-1, FEB 200	1	PREVIO	OUS EDITION MAY	BE USED.	Page _	30 of	32	Pages	I	
						-	Adob	e Profes	sional 8.0		

	CONTRACT	DATA RI (1 Data		Form Approved OMB No. 0704-0188						
data sources, gatherin other aspect of this (0704-0188). Respon of information if it do	ng and maintaining the da collection of information idents should be aware th	ata needed, au n, including s hat notwithsta y valid OMB c	nd completing and r suggestions for red anding any other pro ontrol number. Ple	eviewing the collection of ucing the burden, to the ovision of law, no person sl ase do not return your forr	information. Department hall be subject	g the time for reviewing instr Send comments regarding the of Defense, Executive Servet to any penalty for failing to ve organization. Send complete	his burder ices Dire comply v	n estimat ctorate with a co	te or any	
A. CONTRACT I	<b>INE ITEM NO.</b> 001	B. EXHIE	BIT A	C. CATEGORY: TDP TM	отн	Regulatory docu	uments			
D. SYSTEM/ITE			E. CONTRACT		F. CONT	RACTOR				
1. DATA ITEM NO.	Therapeutics 2. TITLE OF DATA ITEN	vi	W911	QY21C0016	3. SUBTITL	Lilly				17. PRICE GROUP
A030	Press Releases				0,000,000	-				
	Acquisition Document No or format acceptal		5. CONTRACT RE	FERENCE	•	6. REQUIRING OFFICE				18. ESTIMATED TOTAL PRICE
7. DD 250 REQ	9. DIST STATEMENT	10. FREQU	ENCY	12. DATE OF FIRST SUI	MISSION	14. DISTRIB				
	REQUIRED	see	remarks	see remar			t	. COPIE	S	
8. APP CODE		11. AS OF	DATE	13. DATE OF SUBSEQU SUBMISSION		a. ADDRESSEE	Draft		nal	
16. REMARKS				see remar	ζS	BARDA	1	Reg	Repro	
	es to accurately and	factually r	enresent the wo	ork conducted under	this	JPEO CBRND	1			
_	-	-	-	AO has received and			1	<u> </u>	+	
-				s than 5 business day						
the issuance of t				-	-					
				rately and factually 1	represent					
	eted under this contr	-								
		ubmitted to	BARDA no la	ter than one (1) cale	idar day					
prior to its releas	se									
								<u> </u>	+	I
							1		+	
						15. TOTAL	2	0	0	
G. PREPARED B	Y		H. DATE	I. APPROVE	D BY		J. DA	TE		
							04 6	22		11
DD FORM 14	23-1, FEB 200	1	PREVI	OUS EDITION MAY	DE USED.	Page	31 of Adob		Pages sional 8.0	

## **INSTRUCTIONS FOR COMPLETING DD FORM 1423**

(See DoD 5010.12-M for detailed instructions.)

	FOR THE CONTRACTOR
FOR GOVERNMENT PERSONNEL	
Item A. Self-explanatory.	Item 17. Specify appropriate price group from one of the following groups of effort in developing estimated prices for each data item
Item B. Self-explanatory.	listed on the DD Form 1423.
Item C. Mark (X) appropriate category: TDP - Technical Data Package; TM - Technical Manual; Other - other category of data, such as "Provisioning,""Configuration Management," etc.	<ul> <li>a. Group I. Definition - Data which is not otherwise essential to the contractor's performance of the primary contracted effort</li> </ul>
Item D. Enter name of system/item being acquired that data will support.	(production, development, testing, and administration) but which is required by DD Form 1423.
Item E. Self-explanatory (to be filled in after contract award).	
Item F. Self-explanatory (to be filled in after contract award).	Estimated Price - Costs to be included under Group I are
Item G. Signature of preparer of CDRL.	those applicable to preparing and assembling the data item in conformance with Government requirements, and the
Item H. Date CDRL was prepared.	administration and other expenses related to reproducing and delivering such data items to the Government.
Item I. Signature of CDRL approval authority.	
Item J. Date CDRL was approved.	b. Group II. Definition - Data which is essential to the performance of the primary contracted effort but the contractor is
Item 1. See DoD FAR Supplement Subpart 4.71 for proper numbering.	required to perform additional work to conform to Government requirements with regard to depth of content, format, frequency of
Item 2. Enter title as it appears on data acquisition document cited in Item 4.	submittal, preparation, control, or quality of the data item.
<b>Item 3.</b> Enter subtitle of data item for further definition of data item (optional entry).	Estimated Price - Costs to be included under Group II are those incurred over and above the cost of the essential data item without conforming to Covernment requirements and the
<b>Item 4.</b> Enter Data Item Description (DID) number, military specification number, or military standard number listed in DoD 5010.12-L (AMSDL), or one-time DID number, that defines data content and format requirements.	without conforming to Government requirements, and the administrative and other expenses related to reproducing and delivering such data item to the Government.
<b>Item 5.</b> Enter reference to tasking in contract that generates requirement for the data item (e.g., Statement of Work paragraph number).	c. Group III. Definition - Data which the contractor must develop for his internal use in performance of the primary
<b>Item 6.</b> Enter technical office responsible for ensuring adequacy of the data item.	contracted effort and does not require any substantial change to conform to Government requirements with regard to depth of content, format, frequency of submittal, preparation, control, and
Item 7. Specify requirement for inspection/acceptance of the data item by the Government.	quality of the data item.
Item 8. Specify requirement for approval of a draft before preparation of the final data item.	Estimated Price - Costs to be included under Group III are the administrative and other expenses related to reproducing and
<b>Item 9.</b> For technical data, specify requirement for contractor to mark the appropriate distribution statement on the data (ref. DoDD 5230.24).	delivering such data item to the Government.
Item 10. Specify number of times data items are to be delivered.	d. Group IV. Definition - Data which is developed by the
Item 11. Specify as-of date of data item, when applicable.	contractor as part of his normal operating procedures and his effort in supplying these data to the Government is minimal.
Item 12. Specify when first submittal is required.	
Item 13. Specify when subsequent submittals are required, when applicable.	Estimated Price - Group IV items should normally be shown on the DD Form 1423 at no cost.
Item 14. Enter addressees and number of draft/final copies to be delivered to each addressee. Explain reproducible copies in Item 16.	
Item 15. Enter total number of draft/final copies to be delivered.	Item 18. For each data item, enter an amount equal to that portion of the total price which is estimated to be attributable to the
<b>Item 16.</b> Use for additional/clarifying information for Items 1 through 15. Examples are: Tailoring of documents cited in Item 4; Clarification of submittal dates in Items 12 and 13; Explanation of reproducible copies in Item 14.; Desired medium for delivery of the data item.	production or development for the Government of that item of data. These estimated data prices shall be developed only from those costs which will be incurred as a direct result of the requirement to supply the data, over and above those costs which would otherwise be incurred in performance of the contract if no data were required. The estimated data prices shall not include any amount for rights in data. The Government's right to use the data shall be governed by the pertinent provisions of the contract.
	shan be governed by the pertinent provisions of the contract.