

2. Contract No. **W15QRN-21-C-0014** 3. Award/Effective Date **12-JAN-2021** 4. Order Number 5. Solicitation Number 6. Solicitation Issue Date

7. For Solicitation Information Call: **(b) (6)** A. Name **(b) (6)** B. Telephone Number (No Collect Calls) **(b) (6)** 8. Offer Due Date/Local Time

9. Issued By **ARMY CONTRACTING COMMAND - NJ** Code **W15QRN** 10. This Acquisition is Unrestricted OR Set Aside: % For:
PICATINNY ARSENAL, NJ 07906-5000
 Small Business Women-Owned Small Business (WOSB) Eligible Under the Women-Owned Small Business Program
 Hubzone Small Business EDWOSB
 Service-Disabled Veteran-Owned Small Business NAICS: 325414
 8(A) Size Standard:

11. Delivery For FOB Destination Unless Block Is Marked See Schedule 12. Discount Terms
 13a. This Contract Is A Rated Order Under DPAS (15 CFR 700) 13b. Rating **NONE**

14. Method Of Solicitation RFQ IFB RFP
 15. Deliver To **SEE SCHEDULE** Code 16. Administered By **ACC NJ** Code **W15QRN**
BLDG 10 PHIPPS RD
PICATINNY ARSENAL, NJ 07806-5000

Telephone No. **(b) (6)**
 17a. Contractor/Offeror Code **544D9** Facility **REGENERON PHARMACEUTICALS, INC.**
777 OLD SAW MILL RIVER RD
TARRYTOWN, NY 10591-6717
 18a. Payment Will Be Made By **DPAS-INDY VP GFEBB** Code **HQ0490**
8899 E. 56TH STREET
INDIANAPOLIS IN 46249-3800

17b. Check If Remittance Is Different And Put Such Address In Offer 18b. Submit Invoices To Address Shown In Block 18a Unless Block Below Is Checked See Addendum

19. Item No.	20. Schedule Of Supplies/Services	21. Quantity	22. Unit	23. Unit Price	24. Amount
	SEE SCHEDULE				
(Use Reverse and/or Attach Additional Sheets As Necessary)					

25. Accounting And Appropriation Data **SEE CONTRACT ADMINISTRATION DATA** 26. Total Award Amount (For Govt. Use Only) **\$2,625,000,000.00**

27a. Solicitation Incorporates By Reference FAR 52.212-1, 52.212-4, FAR 52.212-3 And 52.212-5 Are Attached. Addenda Are Are Not Attached.
 27b. Contract/Purchase Order Incorporates By Reference FAR 52.212-4. FAR 52.212-5 Is Attached. Addenda Are Are Not Attached.

28. Contractor Is Required To Sign This Document And Return 2 Copies to Issuing Office. Contractor Agrees To Furnish And Deliver All Items Set Forth Or Otherwise Identified Above And On Any Additional Sheets Subject To The Terms And Conditions Specified. 29. Award Of Contract: Ref. _____ Offer Dated _____. Your Offer On Solicitation (Block 5), Including Any Additions Or Changes Which Are Set Forth Herein, Is Accepted As

(b) (6) 31 **(b) (6)** Officer)
 31c. Date Signed **12-JAN-2021**

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEM Offeror To Complete Block 12, 17, 23, 24, & 30				1. Requisition Number SEE SCHEDULE		Page 1 Of 32			
2. Contract No. W15QKN-21-C-0014		3. Award/Effective Date 2021JAN12		4. Order Number		5. Solicitation Number		6. Solicitation Issue Date	
7. For Solicitation Information Call:		A. Name (b) (6)			B. Telephone Number (No Collect Calls) (b) (6)		8. Offer Due Date/Local Time		
9. Issued By ARMY CONTRACTING COMMAND - NJ PICATINNY ARSENAL, NJ 07806-5000 Code W15QKN				10. This Acquisition is <input type="checkbox"/> Unrestricted OR <input type="checkbox"/> Set Aside: % For: <input type="checkbox"/> Small Business <input type="checkbox"/> Women-Owned Small Business (WOSB) Eligible Under the Women-Owned Small Business Program <input type="checkbox"/> Hubzone Small Business <input type="checkbox"/> EDWOSB <input type="checkbox"/> Service-Disabled Veteran-Owned Small Business NAICS: 325414 <input type="checkbox"/> 8(A) Size Standard:					
11. Delivery For FOB Destination Unless Block Is Marked <input type="checkbox"/> See Schedule			12. Discount Terms			13a. This Contract Is A Rated Order Under DPAS (15 CFR 700)		13b. Rating NONE	
15. Deliver To SEE SCHEDULE Code				16. Administered By ACC NJ BLDG 10 PHIPPS RD PICATINNY ARSENAL, NJ 07806-5000 Code W15QKN					
17a. Contractor/Offeror Code 544P9 REGENERON PHARMACEUTICALS, INC. 777 OLD SAW MILL RIVER RD TARRYTOWN, NY 10591-6717 Facility			18a. Payment Will Be Made By DFAS-INDY VP GFEB5 8899 E. 56TH STREET INDIANAPOLIS IN 46249-3800 Code HQ0490						
17b. Check If Remittance Is Different And Put Such Address In Offer <input type="checkbox"/>				18b. Submit Invoices To Address Shown In Block 18a Unless Block Below Is Checked <input type="checkbox"/> See Addendum					
19. Item No.		20. Schedule Of Supplies/Services			21. Quantity	22. Unit	23. Unit Price		24. Amount
		SEE SCHEDULE							
(Use Reverse and/or Attach Additional Sheets As Necessary)									
25. Accounting And Appropriation Data SEE CONTRACT ADMINISTRATION DATA							26. Total Award Amount (For Govt. Use Only) \$2,625,000,000.00		
<input type="checkbox"/> 27a. Solicitation Incorporates By Reference FAR 52.212-1, 52.212-4, FAR 52.212-3 And 52.212-5 Are Attached. Addenda <input type="checkbox"/> Are <input type="checkbox"/> Are Not Attached.					<input type="checkbox"/> 29. Award Of Contract: Ref. _____ Offer Dated _____. Your Offer On Solicitation (Block 5), Including Any Additions Or Changes Which Are Set Forth Herein, Is Accepted As To Items:				
<input checked="" type="checkbox"/> 27b. Contract/Purchase Order Incorporates By Reference FAR 52.212-4, FAR 52.212-5 Is Attached. Addenda <input checked="" type="checkbox"/> Are <input type="checkbox"/> Are Not Attached.									
<input checked="" type="checkbox"/> 28. Contractor Is Required To Sign This Document And Return <u>2</u> Copies To Issuing Office. Contractor Agrees To Furnish And Deliver All Items Set Forth Or Otherwise Identified Above And On Any Additional Sheets Subject To The Terms And Conditions Specified.									
30a. Signature Of Offeror/Contractor				31a. United States Of America (Signature Of Contracting Officer) /SIGNED/					
30b. Name And Title Of Signer (Type Or Print)			30c. Date Signed		31b. Name Of Contracting Officer (Type Or Print) (b) (6)			31c. Date Signed 2021JAN12	

19. Item No.	20. Schedule Of Supplies/Services	21. Quantity	22. Unit	23. Unit Price	24. Amount

32a. Quantity In Column 21 Has Been

Received Inspected Accepted, And Conforms To The Contract, Except As Noted: _____

32b. Signature Of Authorized Government Representative		32c. Date	32d. Printed Name and Title of Authorized Government Representative				
32e. Mailing Address of Authorized Government Representative			32f. Telephone Number of Authorized Government Representative				
			32g. E-Mail of Authorized Government Representative				
33. Ship Number		34. Voucher Number	35. Amount Verified Correct For	36. Payment		37. Check Number	
Partial	Final			<input type="checkbox"/> Complete <input type="checkbox"/> Partial <input type="checkbox"/> Final			
38. S/R Account No.		39. S/R Voucher Number	40. Paid By				
41a. I Certify This Account Is Correct And Proper For Payment			42a. Received By (Print)				
41b. Signature And Title Of Certifying Officer			41c. Date		42b. Received At (Location)		
					42c. Date Rec'd (YY/MM/DD)		42d. Total Containers

Name of Offeror or Contractor: REGENERON PHARMACEUTICALS, INC.

SUPPLEMENTAL INFORMATION

Buyer Name: (b) (6)
Buyer Office Symbol/Telephone Number: (b) (6)
Type of Contract 1: Firm Fixed Price
Kind of Contract: Supply Contracts and Priced Orders
Type of Business: Large Business Performing in U.S.
Surveillance Criticality Designator: A
Contract Expiration Date: 2022JAN11

*** End of Narrative A0000 ***

Executive Summary

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

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

In July 2020, the Department of Defense (DoD) awarded an Other Transaction Agreement under the authority 10 USC 2371b to Regeneron to manufacture and sell drug product to the Government, and to distribute such drug product for the Government in the U.S. These manufacturing production activities included manufacturing at-scale, filling and finishing, and storage and shipping of REGN10987 and REGN10933 as a therapeutic cocktail (casirivimab and imdevimab) to treat COVID-19 infected patients. On November 21, 2020, Regeneron announced that the antibody cocktail casirivimab and imdevimab administered together, received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA).

2. Contract Description: The U.S Army Contracting Command - New Jersey (CCNJ), on behalf of the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) and the Biomedical Advanced Research and Development Authority (BARDA), will execute a contract for the procurement of up to 1,250,000 doses of the EUA authorized (or Biologics License Application (BLA) approved) casirivimab and imdevimab therapeutic, enough to treat much of the targeted US population currently or projected to be infected over the coming months. This contract award is a sole-source Firm Fixed Price (FFP) contract pursuant to FAR 6.302-2, "Unusual and Compelling Urgency," to Regeneron Pharmaceuticals, Inc., Tarrytown, New York. This action has a total FFP value of \$2,625,000,000.00. The price per dose is inclusive of storage, distribution, insurance and administration costs, costs associated with obtaining and maintaining regulatory authorization for the product (packaging, labeling, and informational materials), and Regeneron's manufacturing facilities. The period of performance for this contract is twelve (12) months, to include distribution of the product.

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

4. The Regeneron Draft Small Business Subcontracting Plan, dated 30 November 2020, is hereby incorporated into this contract by attachment. It is noted that this draft plan will be replaced by the plan that is ultimately approved by the United States Department of Veterans Affairs.

5. Contract Point of Contact:

(b) (6)

(b) (6)

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*** END OF NARRATIVE A0001 ***

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Name of Offeror or Contractor: REGENERON PHARMACEUTICALS, INC.

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
	<p>PRON: CB1RD14381 PRON AMD: 01 ACRN: AB PSC: 6505</p> <p><u>Packaging and Marking</u></p> <p><u>Inspection and Acceptance</u> INSPECTION: Destination ACCEPTANCE: Destination</p> <p><u>Deliveries or Performance</u> DOC SUPPL REL CD MILSTRIP ADDR SIG CD MARK FOR TP CD 001 W56XNH10011002 75A501 J 3 DEL REL CD QUANTITY DEL DATE 001 (b) (4) (b) (4)</p> <p>FOB POINT: Destination</p> <p>SHIP TO: (75A501) OFFICE OF ACQ MGMT POLICY HUBERT HUMPHREY BLDG 200 INDEPENDENCE AVENUE SW ROOM 336E WASHINGTON, DC, 20201</p> <p>The parties will coordinate ordering through centralized distribution via the established Memorandum of Understanding between Regeneron, ASPR, and AmerisourceBergen. Exact ship-to locations for product will be identified through this coordinated process.</p> <p>(End of narrative F001)</p>				
0001AC	<p><u>COVID-19 THERAPEUTIC (REGN10987 AND REGN10933)</u></p> <p>COMMODITY NAME: COVID THERAPEUTIC CLIN CONTRACT TYPE: Firm Fixed Price PRON: CB1RD41544 PRON AMD: 01 ACRN: AC PSC: 6505</p> <p><u>Packaging and Marking</u></p> <p><u>Inspection and Acceptance</u> INSPECTION: Destination ACCEPTANCE: Destination</p> <p><u>Deliveries or Performance</u> DOC SUPPL REL CD MILSTRIP ADDR SIG CD MARK FOR TP CD 001 W56XNH10011003 75A501 J 3 DEL REL CD QUANTITY DEL DATE</p>	(b) (4)	EA	\$ 2,100.00000	\$ (b) (4)

CONTINUATION SHEET

Reference No. of Document Being Continued
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 PIIN/SIIN MOD/AMD

Name of Offeror or Contractor: REGENERON PHARMACEUTICALS, INC.

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
	<p>001 (b) (4) (b) (4)</p> <p>FOB POINT: Destination</p> <p>SHIP TO: (75A501) OFFICE OF ACQ MGMT POLICY HUBERT HUMPHREY BLDG 200 INDEPENDENCE AVENUE SW ROOM 336E WASHINGTON,DC,20201</p> <p>The parties will coordinate ordering through centralized distribution via the established Memorandum of Understanding between Regeneron, ASPR, and AmerisourceBergen. Exact ship-to locations for product will be identified through this coordinated process.</p> <p>(End of narrative F001)</p>				
0002	<p><u>DD1423 CDRLS A001 THROUGH A030</u></p> <p>The ELIN below is associated with the Data Item numbers in the Contract Data Requirements List (CDRL, DD 1423), in Section J. Reference individual CDRLs for applicable instructions and delivery dates.</p> <p>(End of narrative A001)</p>				
A001	<p><u>DD1423 CDRLS A001 THROUGH A030</u></p> <p>SERVICE REQUESTED: DATA ITEMS CLIN CONTRACT TYPE: Firm Fixed Price</p> <p><u>Inspection and Acceptance</u> INSPECTION: Destination ACCEPTANCE: Destination</p> <p><u>Deliveries or Performance</u> DLVR SCH PERF COMPL <u>REL CD QUANTITY DATE</u> 001 1 SEE DD FORM 1423</p>	1	LO		\$ (b) (4)

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MOD/AMD

Name of Offeror or Contractor: REGENERON PHARMACEUTICALS, INC.

DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

STATEMENT OF WORK

Production of Regeneron Therapeutic in Support of National Emergency Response to Coronavirus 2019 (COVID-19)

C.1 Scope: The Department of Defense (DoD) and Department of Health and Human Services (DHHS), in support of Operation Warp Speed (OWS) and national emergency response to the Coronavirus Disease 2019 (COVID-19), requires the production of Regeneron therapeutic cocktail REGN10987 and REGN10933 (casirivimab and imdevimab) on a commercial item basis, up to 1,250,000 doses to treat members of the DoD and the general population infected with the SARS CoV-2 Virus.

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

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

In July 2020, the DoD awarded an Other Transaction Agreement under the authority of 10 USC 2371b to Regeneron to manufacture and sell drug product to the Government, and to distribute such drug product for the Government in the U.S. These manufacturing production activities included manufacturing at-scale, filling and finishing, and storage and shipping of REGN10987 and REGN10933 as a therapeutic cocktail to treat COVID-19 infected patients. On November 21, 2020, Regeneron announced that the antibody cocktail casirivimab and imdevimab administered together, has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA).

As part of DHHS preparedness and response activities, DHHS seeks to purchase up to 1,250,000 doses of the EUA authorized (or Biologics License Application (BLA) approved) casirivimab and imdevimab therapeutic, enough to treat much of the targeted US population currently or projected to be infected over the coming months.

C.2 Objectives and Quantity: The contractor shall produce up to 1,250,000 doses of therapeutic, and the Government will purchase all such doses available in Vendor-Managed Inventory (VMI) by the applicable date set forth below:

No Later Than (NLT) June 30, 2021. The Government will consider extending the time for delivery to NLT September 30, 2021, if the contractor is unable to complete delivery to VMI by June 30, 2021, after making a good faith effort to do so. However, prior to any extension to the delivery schedule, the contractor shall coordinate with the Government to determine an appropriate path forward, aligning with Government needs. The contractor shall comply with the procedures of FAR 52.212-4(f), Excusable Delays.

C.3 Requirements:

C.3.1 Therapeutic: The contractor shall distribute the product to Government designated sites as directed by the Government, EUA authorized finished drug product in vials in accordance with the products storage and handling requirements in the EUA, including temperature controls. This shall include storage and distribution activities. Regeneron will engage one or more third party service providers (each a Distributor) to perform storage and distribution activities for drug product at the direction of the Government. The Government will be solely responsible for all allocation determinations related to drug product, including allocation to end users and communication of such allocation determinations to the Distributor. Unless otherwise mutually agreed upon by the parties, drug product shall be shipped to the Government or distributed, as applicable, solely within the United States (including its territories and possessions). The contractor shall (b) (4), until the product is distributed to the end user (e.g., the hospital, infusion center or other end-user). To the extent that Regeneron is responsible for the correction, repair or replacement of Government property held in vendor-managed inventory or in distribution and in the possession of the Distributor, (b) (4), the Government will (b) (4) of such property. The parties will coordinate ordering through centralized distribution via the established Memorandum of Understanding between Regeneron, Assistant Secretary for Preparedness and Response (ASPR), and AmerisourceBergen. Storage and distribution activities under the EUA shall be supported under this agreement through the end of the period of performance.

C.3.2 Product Development Manufacturing Reports and Projections: Regeneron will provide manufacturing reports and manufacturing dose tracking projections/actuals, in the format and having the content mutually agreed upon by the Government and Regeneron. Regeneron will update the reports (b) (4) during manufacturing campaigns and upon manufacturing deliverable submission during COVID-19 response operations (where a Public Health Emergency has been declared), with the first deliverable submission within (b) (4) of award. For clarity, the reports described in this section apply to Formulated Drug Substance and Drug Product prior to delivery and acceptance by the Government. Tracking reports for product following delivery and acceptance, shall be set forth in the Memorandum of Understanding between Regeneron, ASPR, and AmerisourceBergen.

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otherwise mutually agreed to by the parties, the product shall not be sold to the Government for use in any other approved or authorized indication or dose exceeding 2400mg/mAb.

Public Disclosures: Notwithstanding any other provision in this contract, the contractor may publicly release any information related to this contract without prior approval to the extent necessary to satisfy or address regulatory requirements, contractual obligations to third parties, and the public interest in data about the safety or efficacy of the product.

Public Readiness and Emergency Preparedness (PREP) Act: The Government will ensure that no product purchased under this contract is used outside the United States (including its territories or possessions) or in a way that is not protected from liability by a declaration issued under the PREP Act that is active at the time of use.

C.9 Government Technical Point of Contact:

(b) (6)
HHS BARDA

(b) (6)
[Redacted]

*** END OF NARRATIVE C0001 ***

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Name of Offeror or Contractor: REGENERON PHARMACEUTICALS, INC.

INSPECTION AND ACCEPTANCE

	<u>Regulatory Cite</u>	<u>Title</u>	<u>Date</u>
1	52.246-2	INSPECTION OF SUPPLIES--FIXED-PRICE	AUG/1996
2	52.246-16	RESPONSIBILITY FOR SUPPLIES	APR/1984

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Name of Offeror or Contractor: REGENERON PHARMACEUTICALS, INC.

DELIVERIES OR PERFORMANCE

	<u>Regulatory Cite</u>	<u>Title</u>	<u>Date</u>
1	52.247-34	F.O.B. DESTINATION	NOV/1991

Any deliverables identified within this section are only required to be delivered should they differ from what has been previously delivered under Regeneron's prototype agreement, MCDC2008-005.

I. Supply Chain Resiliency Plan

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

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

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

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

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

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

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

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

a) Production rates and lead times shall be understood and communicated to the Contracting Officer (CO) or the Technical Point of Contact (TPOC) as necessary.

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

E. Reports for critical items shall include the following information:

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

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

II. Manufacturing Data Requirements

A. The contractor shall submit within (b) (4) of contract award, detailed data regarding project materials, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material;

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location and nature of work performed at manufacturing, processing, and fill/finish sites; and location and nature of clinical studies sites (it being understood that such information already has been provided). The Government may provide a table in tabular format for the contractor to be used to submit such data, which would include but not be limited to the following:

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

III. Product Development Source Material and Manufacturing Reports and Projections

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

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

C. Reporting Procedures and Due Dates:

1. Contractor will submit Product Development Source Material Report:

- a) Within (b) (4) of contract award
- b) Within (b) (4) of substantive changes made to sources and/or materials
- c) On the (b) (4) contract anniversary, if no substantive changes have been made in the preceding (b) (4) period

2. The Government will provide written comments to the Product Development Source Material and Manufacturing Report within (b) (4) after the submission.

a) If corrective action is recommended, the contractor must address all concerns raised by the Government in writing.

3. Product Development and Source Material report to be submitted via spreadsheet; Dose Tracking can be completed via spreadsheet or other format (e.g. XML or JSON) as agreed to by the Government and contractor.

4. The contractor will update the Dose Tracking Template weekly during manufacturing campaigns and upon manufacturing deliverable submission during COVID-19 response operations (where a Public Health Emergency has been declared), with the first deliverable submission within (b) (4) of award.

IV. Contractor Locations

A. 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.

The contractor will submit Work Locations Report:

- a) Within (b) (4) of contract award
- b) Within (b) (4) after a substantive location or capabilities change
- c) Within (b) (4) of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern by the WHO

V. Access and General Protection/Security Policy and Procedures

This standard language text is applicable to ALL employees working on critical information related to Operation Warp Speed (OWS) with an area of performance within a Government controlled installation, facility or area. Employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The performer also shall provide all information required for background checks necessary to access critical information related to OWS, and to meet Government installation access requirements to be accomplished by installation Director of

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Emergency Services or Security Office. The workforce must comply with all personnel identity verification requirements as directed by the Government and/or local policy. In addition to the changes otherwise authorized by the changes clause of this contract, should the security status of OWS change, the Government may require changes in performer security matters or processes. In addition to the industry standards for employment background checks, the contractor must be willing to have key individuals, in exceptionally sensitive positions, identified for additional vetting by the United States Government.

VI. Operational Security (OPSEC)

The performer shall develop an OPSEC Standard Operating Procedure (SOP)/Plan within (b) (4) of project award to be reviewed and approved by the responsible Government OPSEC officer. This plan will be submitted to the TPOC 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.

VII. 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 (b) (4) 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 (b) (4) to the 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 (b) (4) 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 CO a letter certifying compliance to the elements outlined in the Final Security Plan.

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

Security Requirements:

1. Facility Security Plan

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

A. Security Administration

- organization chart and responsibilities
- written security risk assessment for site
- threat levels with identification matrix (High, Medium, or Low)
- enhanced security procedures during elevated threats
- liaison procedures with law enforcement
- annual employee security education and training program

B. Personnel Security

- policies and procedures
- candidate recruitment process
- background investigations process
- employment suitability policy
- employee access determination
- rules of behavior/conduct
- termination procedures
- non-disclosure agreements

C. Physical Security Policies and Procedures

- internal/external access control
- protective services
- identification/badging
- employee and visitor access controls

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- parking areas and access control
- perimeter fencing/barriers
- product shipping, receiving and transport security procedures
- facility security lighting
- restricted areas
- signage
- intrusion detection systems
- alarm monitoring/response
- closed circuit television
- product storage security
- other control measures as identified

D. Information Security

- identification and marking of sensitive information
- access control
- storage of information
- document control procedures
- retention/destruction requirements

E. Information Technology/Cyber Security Policies and Procedures

- intrusion detection and prevention systems
- threat identification
- employee training (initial and annual)
- encryption systems
- identification of sensitive information/media
- password policy (max days 90)
- lock screen time out policy (minimum time 20 minutes)
- removable media policy
- laptop policy
- removal of IT assets for domestic/foreign travel
- access control and determination
- VPN procedures
- WiFi and Bluetooth disabled when not in use
- system document control
- system backup
- system disaster recovery
- incident response
- system audit procedures
- property accountability

2. Site Security Master Plan

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

3. Site Threat/Vulnerability/Risk Assessment

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

4. Physical Security**A. Closed Circuit Television (CCTV) Monitoring**

- a) Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored.
- b) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract.
- c) Video recordings must be maintained for a minimum of 30 days.
- d) CCTV surveillance system must be on emergency power backup.

B. Facility Lighting

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- a) Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings.
- b) Lighting must have emergency power backup.
- c) Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.

C. Shipping and Receiving

- a) Must have CCTV coverage and an electronic access control system.
- b) Must have procedures in place to control access and movement of drivers picking up or delivering shipments.
- c) Must identify drivers picking up Government products by government issued photo identification.

D. Access Control

- a) Must have an electronic intrusion detection system with centralized monitoring.
- b) Responses to alarms must be immediate and documented in writing.
- c) Employ an electronic system (i.e., card key) to control access to areas where assets critical to the contract are located (facilities, laboratories, clean rooms, production facilities, warehouses, server rooms, records storage, etc.).
- d) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas.
- e) Must have a system that provides a historical log of all key access transactions and kept on record for a minimum of (b) (4)
- f) Must have procedures in place to track issuance of access cards to employees and the ability to deactivate cards when they are lost or an employee leaves the company.
- g) Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of (b) (4)
- h) Should have written procedures to prevent employee piggybacking access.
- i) Critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access.
- j) Must have a written manual key accountability and inventory process.
- k) Physical access controls should present a layered approach to critical assets within the facility.

E. Employee/Visitor Identification

- a) Should issue company photo identification to all employees.
- b) Photo identification should be displayed above the waist anytime the employee is on company property.
- c) Visitors should be sponsored by an employee and must present government issued photo identification to enter the property.
- d) Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises at all times.

F. Security Fencing

Requirements for security fencing will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.

G. 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.

H. Protective Security Forces Operations

- a) Must have in-service training program.
- b) Must have Use of Force Continuum.
- c) Must have communication systems available (i.e., landline on post, cell phones, handheld radio, and desktop computer).
- d) Must have Standing Post Orders.
- e) Must wear distinct uniform identifying them as security officers.

5. Security Operations

A. 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 (b) (4) POC information for LE Officer that attended the meeting must be documented.
- c) Implement procedures for receiving and disseminating threat information.

B. Training

- a) Conduct new employee security awareness training.

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b) Conduct and maintain records of annual security awareness training.

C. 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

A. 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.

B. Hiring and Retention Standards

- a) Detailed policies and procedures concerning hiring and retention of employees, employee conduct, and off boarding procedures.
- b) Off Boarding procedures should be accomplished within 24 hours of employee leaving the company. This includes termination of all network access.

7. Information Security

A. Physical Document Control

- a) Applicable documents shall be identified and marked as procurement sensitive, proprietary, or with appropriate Government markings.
- b) Sensitive, proprietary, and Government documents should be maintained in a lockable filing cabinet/desk or other storage device and not be left unattended.
- c) Access to sensitive information should be restricted to those with a need to know.

B. Document Destruction

- a) Documents must be destroyed using approved destruction measures (i.e, shredders/approved third party vendors / pulverizing / incinerating).

8. Information Technology and Cybersecurity

A. 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).

B. Access Control

- a) Limit information system access to authorized users.
- b) Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access.
- c) Limit physical access to information systems, equipment, and server rooms with electronic access controls.
- d) Limit access to/verify access to use of external information systems.

C. Training

- a) Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.

D. 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 of (b) (4) .

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- 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.

E. Configuration Management

- a) Establish and enforce security configuration settings.
- b) Implement sub networks for publically accessible system components that are physically or logically separated from internal networks.

F. Contingency Planning

- a) Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times.

G. 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.

H. Media and Information Protection

- a) Protect information system media, both paper and digital.
- b) Limit access to information on information systems media to authorized users.
- c) Sanitize and destroy media no longer in use.
- d) Control the use of removable media through technology or policy.

I. Physical and Environmental Protection

- a) Limit access to information systems, equipment, and the respective operating environments to authorized individuals.
- b) Intrusion detection and prevention system employed on IT networks.
- c) Protect the physical and support infrastructure for all information systems.
- d) Protect information systems against environmental hazards.
- e) Escort visitors and monitor visitor activity.

J. Network Protection

- a) Employ intrusion prevention and detection technology with immediate analysis capabilities.

9. Transportation Security

Description: Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage.

A. Drivers

- a) Drivers must be vetted in accordance with Government Personnel Security Requirements.
- b) Drivers must be trained on specific security and emergency procedures.
- c) Drivers must be equipped with backup communications.
- d) Driver identity must be 100 percent confirmed before the pick-up of any Government product.
- e) Drivers must never leave Government products unattended, and two drivers may be required for longer transport routes or critical products during times of emergency.
- f) Truck pickup and deliveries must be logged and kept on record for a minimum of (b) (4).

B. Transport Routes

- a) Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency.
- b) Transport routes should be continuously evaluated based upon new threats, significant planned events, weather, and other situations that may delay or disrupt transport.

C. Product Security

- a) Government products must be secured with tamper resistant seals during transport, and the transport trailer must be locked and sealed.
 - Tamper resistant seals must be verified as secure after the product is placed in the transport vehicle.

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- b) Government products should be continually monitored by GPS technology while in transport, and any deviations from planned routes should be investigated and documented.
- c) Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.

10. Security Reporting Requirements

Description: The partner facility shall notify the Government Security Team within (b) (4) of any activity or incident that is in violation of established security standards or indicates the loss or theft of Government products. The facts and circumstances associated with these incidents will be documented in writing for Government review.

11. Security Audits

Description: The partner facility agrees to formal security audits conducted at the discretion of the Government. Security audits may include both prime and subcontractor.

*** END OF NARRATIVE F0001 ***

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CONTRACT ADMINISTRATION DATA

LINE	PRON/ AMS CD/ MIPR/ <u>ITEM</u> <u>GFEBs ATA</u>	<u>OBLG</u> <u>STAT</u>	<u>JO NO/</u> <u>ACCT ASSIGN</u>	<u>ACRN</u>	OBLIGATED AMOUNT
0001AA	CB1RD13635	2	S.0074658.5.40	AA	\$ (b) (4)
0001AB	CB1RD14381	2	S.0074658.5.40.1	AB	\$ (b) (4)
0001AC	CB1RD41544	2	S.0074658.5.40.2	AC	\$ (b) (4)
TOTAL					\$ 2,625,000,000.00

<u>ACRN</u>	<u>ACCOUNTING CLASSIFICATION</u>	OBLIGATED AMOUNT
AA	021 202120222040 A5XAH 654807849FL8D 255Y L071413635 S.0074658.5.40	021001 \$ (b) (4)
AB	021 202120222040 A5XAH 654807849FL8D 255Y L071414381 S.0074658.5.40.1	021001 \$ (b) (4)
AC	021 202120222040 A5XAH 654807849FL8D 255Y L071414544 S.0074658.5.40.2	021001 \$ (b) (4)
TOTAL		\$ 2,625,000,000.00

LINE	<u>ITEM</u>	<u>ACRN</u>	<u>EDI/SFIS ACCOUNTING CLASSIFICATION</u>	OBLIGATED AMOUNT
0001AA	AA	021	202120222040 A5XAH 654807849FL8D 255Y L071413635 S.0074658.5.40	021001
0001AB	AB	021	202120222040 A5XAH 654807849FL8D 255Y L071414381 S.0074658.5.40.1	021001
0001AC	AC	021	202120222040 A5XAH 654807849FL8D 255Y L071414544 S.0074658.5.40.2	021001

<u>Regulatory Cite</u>	<u>Title</u>	<u>Date</u>
1 252.232-7006	WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS	DEC/2018

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) For fixed price line items--

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

Invoice (Contractor Only)

(B) For services that do not require shipment of a deliverable, submit either the Invoice 2-in-1, which meets the requirements for the invoice and receiving report, or the applicable invoice and receiving report, as specified by the Contracting Officer.

Invoice as 2-in-1

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

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

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

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

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

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

Routing Data Table*

Field Name in WAWF	Data to be entered in WAWF
Pay Official DoDAAC	HQ0490
Issue By DoDAAC	W15QKN
Admin DoDAAC	W15QKN
Inspect By DoDAAC	TBD
Ship To Code	TBD
Ship From Code	TBD
Mark For Code	TBD
Service Approver (DoDAAC)	N/A
Service Acceptor (DoDAAC)	N/A
Accept at Other DoDAAC	N/A
LPO DoDAAC	N/A
DCAA Auditor DoDAAC	N/A
Other DoDAAC(s)	N/A

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

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

(g) WAWF point of contact.

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

(b) (6)

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

(End of clause)

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SPECIAL CONTRACT REQUIREMENTS

As this is a commercial contract, any special requirements contained in this section and throughout the contract, are incorporated by addendum.

1. OWS REQUIRED CLAUSE

I. Key Personnel

Any key personnel specified in this contract are considered to be essential to work performance. At least (b) (4) prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts, the Contractor shall notify the CO and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than (b) (4), the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the CO. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties. The following individuals are determined to be key personnel:

Reference Regeneron's Technical Proposal dated 29 December 2020, Section 2.3.1.1, Program Management, for a listing of key personnel

II. Substitution of Key Personnel

The Contractor agrees to assign to the contract those persons whose resumes/CVs were submitted with the proposal who are necessary to fill the requirements of the contract. No substitutions shall be made, except in accordance with this clause.

All requests for substitution must provide a detailed explanation of the circumstance necessitating the proposed substitution, a complete resume for the proposed substitute and any other information requested by the CO to approve or disapprove the proposed substitution. All proposed substitutes must have qualifications that are equal to or higher than the qualifications of the person to be replaced. The CO or authorized representative (TPOC) will evaluate such requests and promptly notify the Contractor of his approval or disapproval thereof.

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

III. Disclosure of Information

Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO in accordance with OWS or other Government policies and/or guidance. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

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

No information related to data obtained from the Government under this contract shall be released or publicized without the prior written consent of the TPOC, 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 Contractors (or its parent corporations) 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.

IV. Publications 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 TPOC for security review prior to submission. The Contractor shall also inform the TPOC when the abstract article or other publication is published, and furnish a copy of it as finally published.

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(b) Unless authorized in writing by the CO, the Contractor shall not display Government logos, including Operating Division or Staff Division logos on any publications.

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

(d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The Contractor shall acknowledge the support of the Government whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part by the U.S. Government under Contract No. W15QKN-21-C-0014. The US Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon."

V. Confidentiality of Information

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

b. The CO 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 CO and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

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

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

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

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

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

All above requirements MUST be passed to all sub-contractors.

VI. Organizational Conflicts of Interest

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

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

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

Whenever performance of this contract provides access to another Contractors proprietary information, the Contractor shall enter into a written agreement with the other entities involved, as appropriate, in order to protect such proprietary information from unauthorized use or disclosure for as long as it remains proprietary; and refrain from using such proprietary information other than as agreed to,

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for example to provide assistance during technical evaluation of other Contractors offers or products under this contract. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the CO within (b) (4) of execution.

2. HEALTH RESOURCE PRIORITY AND ALLOCATIONS SYSTEM (HRPAS)

In order to ensure the success of Regenerons efforts, a priority rating is incorporated into the contract for the procurement of raw materials, consumables, repair parts, and major end item assemblies by Regeneron under Title I of the HRPAS.

Priority Rating: Defense Production Act (DPA) Title I DO-HR

Each rated order executed by Regeneron must include the following:

- (a) The priority rating: DPA Title I DO-HR;
(b) A required delivery date or dates. The words immediately or as soon as possible do not constitute a delivery date;
(c) The written signature on a manually placed order, or the digital signature or name on an electronically placed order, of an individual authorized to sign rated orders for the person placing the order; and
(d) A statement that reads in substance:
(1) This is a rated order certified for national defense use, and you are required to follow all the provisions of the Health Resources Priorities and Allocations System regulation at 45 CFR part 101.
(2) If the rated order is placed in support of emergency preparedness requirements and expedited action is necessary and appropriate to meet these requirements, the following sentences should be added following the statement set forth in paragraph (d)(1) of this section:
(i) This rated order is placed for the purpose of emergency preparedness. It must be accepted or rejected within (b) (4) after receipt of the order if:
A. The order is issued in response to a hazard that has occurred; or
B. If the order is issued to prepare for an imminent hazard, as specified in HRPAS Section 101.33(e).

3. ENSURING SUFFICIENT SUPPLY OF THE PRODUCT

1. In recognition of the Governments 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) Regeneron gives written notice, required to be submitted to the Government no later than (b) (4), of:
i. any formal management decision to terminate manufacturing of this product therapeutic prior to delivery of the minimum required doses to the U.S. Government under this contract, as well as all additional orders accepted by the 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 the U.S. Government under this contract, as well as all additional orders accepted by the 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) Regeneron has submitted an Emergency Use Authorization application under Section 564 of the Food, Drug, and Cosmetic (FD&C) Act or a biologics license application under the provisions of Section 351(a) of the Public Health Service Act (PHSA).

2. If both conditions listed in section 1 occur, Regeneron, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of this therapeutic product with a third party for exclusive sale to the U.S. Government:

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CONTRACT CLAUSES

	<u>Regulatory Cite</u>	<u>Title</u>	<u>Date</u>
1	52.204-13	SYSTEM FOR AWARD MANAGEMENT MAINTENANCE	OCT/2018
2	52.204-18	COMMERCIAL AND GOVERNMENT ENTITY CODE MAINTENANCE	AUG/2020
3	52.212-4	CONTRACT TERMS AND CONDITIONS--COMMERCIAL ITEMS	OCT/2018
4	52.219-16	LIQUIDATED DAMAGES--SUBCONTRACTING PLAN	JAN/1999
5	52.232-40	PROVIDING ACCELERATED PAYMENTS TO SMALL BUSINESS SUBCONTRACTORS	DEC/2013
6	252.203-7000	REQUIREMENTS RELATING TO COMPENSATION OF FORMER DOD OFFICIALS	SEP/2011
7	252.203-7002	REQUIREMENT TO INFORM EMPLOYEES OF WHISTLEBLOWER RIGHTS	SEP/2013
8	252.203-7003	AGENCY OFFICE OF THE INSPECTOR GENERAL	AUG/2019
9	252.204-7003	CONTROL OF GOVERNMENT PERSONNEL WORK PRODUCT	APR/1992
10	252.204-7012	SAFEGUARDING COVERED DEFENSE INFORMATION AND CYBER INCIDENT REPORTING	DEC/2019
11	252.204-7015	NOTICE OF AUTHORIZED DISCLOSURE OF INFORMATION FOR LITIGATION SUPPORT	MAY/2016
12	252.204-7020	NIST SP 800-171 DOD ASSESSMENT REQUIREMENTS	NOV/2020
13	252.205-7000	PROVISION OF INFORMATION TO COOPERATIVE AGREEMENT HOLDERS	DEC/1991
14	252.209-7004	SUBCONTRACTING WITH FIRMS THAT ARE OWNED OR CONTROLLED BY THE GOVERNMENT OF A TERRORIST COUNTRY	MAY/2019
15	252.219-7003	SMALL BUSINESS SUBCONTRACTING PLAN (DOD CONTRACTS)--BASIC	DEC/2019
16	252.225-7012	PREFERENCE FOR CERTAIN DOMESTIC COMMODITIES	DEC/2017
17	252.227-7015	TECHNICAL DATA--COMMERCIAL ITEMS	FEB/2014
18	252.232-7003	ELECTRONIC SUBMISSION OF PAYMENT REQUESTS AND RECEIVING REPORTS	DEC/2018
19	252.232-7010	LEVIES ON CONTRACT PAYMENTS	DEC/2006
20	252.232-7017	ACCELERATING PAYMENTS TO SMALL BUSINESS SUBCONTRACTORS--PROHIBITION ON FEES AND CONSIDERATION	APR/2020
21	252.243-7002	REQUESTS FOR EQUITABLE ADJUSTMENT	DEC/2012
22	252.244-7000	SUBCONTRACTS FOR COMMERCIAL ITEMS	OCT/2020
23	252.247-7023	TRANSPORTATION OF SUPPLIES BY SEA--BASIC	FEB/2019
24	52.212-5	CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS--COMMERCIAL ITEMS	NOV/2020

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

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

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

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

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

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

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

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

___ (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).

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- (5) [Reserved].
- (6) 52.204-14, Service Contract Reporting Requirements (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).
- (7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).
- (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (Jun 2020) (31 U.S.C. 6101 note).
- (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 (Nov 2020) (15 U.S.C. 644).
- (ii) Alternate I (MAR 2020) of 52.219-6.
- (iii) Alternate II (Nov 2011) of 52.219-6.
- (15) (i) 52.219-7, Notice of Partial Small Business Set-Aside (Nov 2020) (15 U.S.C. 644).
- (ii) Alternate I (MAR 2020) of 52.219-7.
- (iii) Alternate II (Mar 2004) of 52.219-7.
- (16) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d) (2) and (3)).
- (17) (i) 52.219-9, Small Business Subcontracting Plan (Jun 2020) (15 U.S.C. 637(d) (4)).
- (ii) Alternate I (Nov 2016) of 52.219-9.
- (iii) Alternate II (Nov 2016) of 52.219-9.
- (iv) Alternate III (Jun 2020) of 52.219-9.
- (v) Alternate IV (Jun 2020) of 52.219-9.
- (18) (i) 52.219-13, Notice of Set-Aside of Orders (MAR 2020) (15 U.S.C. 644(r)).
- (ii) Alternate I (Mar 2020) of 52.219-13.
- (19) 52.219-14, Limitations on Subcontracting (MAR 2020) (15 U.S.C. 637(a) (14)).
- (20) 52.219-16, Liquidated Damages--Subcontracting Plan (JAN 1999) (15 U.S.C. 637(d) (4) (F) (i)).
- (21) 52.219-27, Notice of Total Service-Disabled Veteran-Owned Small Business Set-Aside (MAR 2020) (15 U.S.C. 657 f)
- (22) (i) 52.219-28, Post Award Small Business Program Rerepresentation (Nov 2020) (15 U.S.C. 632(a) (2)).
- (ii) Alternate I (MAY 2020) of 52.219-28.
- (23) 52.219-29 Notice of Total Set-Aside for Economically Disadvantaged Women-Owned Small Business (EDWOSB) Concerns (MAR 2020)

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(15 U.S.C. 637(m)).

___ (24) 52.219-30 Notice of Total Set-Aside for Women-Owned Small Business (WOSB) Concerns Eligible Under the WOSB 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)).

___ (27) 52.222-3, Convict Labor (June 2003) (E.O. 11755).

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

___ (29) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).

X (30) (i) 52.222-26, Equal Opportunity (Sep 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 (July 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 (July 2014) of 52.222-36.

___ (33) 52.222-37, Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Jun 2020) (38 U.S.C. 4212).

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

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

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

___ (36) 52.222-54, Employment Eligibility Verification (Oct 2015). (Executive Order 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 (June, 2016) (E.O. 13693).

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

___ (40) (i) 52.223-13, Acquisition of EPEAT[supreg]-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[supreg]-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[supreg]-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).

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- (45) 52.223-20, Aerosols (June, 2016) (E.O. 13693).
- (46) 52.223-21, Foams (June, 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).
- (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 (Jul 2013) (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)).
- (58) 52.232-33, Payment by Electronic Funds Transfer -- System for Award Management (Oct 2018) (31 U.S.C. 3332).
- (59) 52.232-34, Payment by Electronic Funds Transfer -- Other Than System for Award Management (Jul 2013) (31 U.S.C. 3332).
- (60) 52.232-36, Payment by Third Party (MAY 2014) (31 U.S.C. 3332).
- (61) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).
- (62) 52.242-5, Payments to Small Business Subcontractors (Jan 2017) (15 U.S.C. 637(d)(13)).
- (63) (i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx 1241(b) and 10 U.S.C. 2631).
- (ii) Alternate I (Apr 2003) of 52.247-64.
- (iii) Alternate II (Feb 2006) of 52.247-64.
- (c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or executive orders applicable to acquisitions of commercial items:
- (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) (MAY 2014) (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).

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

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

___ (7) 52.222-55, Minimum Wages Under Executive Order 13658 (Nov 2020) (Executive Order 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 Contractors 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).

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

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(xiii) (A) 52.222-50, Combating Trafficking in Persons (Oct 2020) (22 U.S.C. 7104(g)).

(B) Alternate I (Mar 2015) of 52.222-50 (22 U.S.C. 7104(g)).

(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).

(xvii) 52.222-55, Minimum Wages Under Executive Order 13658 (Nov 2020) (Executive Order 13658).

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

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

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

(xx) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Jul 2013) (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)

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LIST OF ATTACHMENTS

<u>List of</u> <u>Addenda</u>	<u>Title</u>	<u>Date</u>	<u>Number</u> <u>of Pages</u>	<u>Transmitted By</u>
Exhibit A	CONTRACT DATA REQUIREMENTS LIST	07-JAN-2021	033	EMAIL
Attachment 0001	SF LLL DISCLOSURE OF LOBBYING ACTIVITIES	04-JAN-2021	001	EMAIL
Attachment 0002	REGENERON DRAFT SUBCONTRACTING PLAN	30-NOV-2020	009	EMAIL

W15QKN-21-C-
Exhibit A
Contract Data Requirements List
CDRLs

Date: 07 January 2021
of pages: 32

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved

OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 110 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.

A. CONTRACT LINE ITEM NO. 0001	B. EXHIBIT A	C. CATEGORY: TDP <input checked="" type="checkbox"/> IM _____ OTHER _____
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D. SYSTEM/ITEM Therapeutics	E. CONTRACT/PR NO. W15QKN21C	F. CONTRACTOR Regeneron
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1. DATA ITEM NO. A009	2. TITLE OF DATA ITEM Draft Technical Progress Report	3. SUBTITLE
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4. AUTHORITY (Data Acquisition Document No.) DI-MISC-80711	5. CONTRACT REFERENCE SOW	6. REQUIRING OFFICE BARDA
--	-------------------------------------	-------------------------------------

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY see remarks	12. DATE OF FIRST SUBMISSION see remarks	14. DISTRIBUTION		
8. APP CODE		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION see remarks	a. ADDRESSEE	b. COPIES	
					Draft	Final

16. REMARKS A draft Final Technical Progress Report containing a summation of the work performed over the entire Agreement. This report shall be in sufficient detail to fully describe the progress achieved under all milestones. Report should contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained during the Agreement. Descriptions and rationale for activities and milestones that were not completed as planned should be provided. The draft report shall be duly marked as 'Draft'	BARDA	1			
	JPEO CBRND	1			
	15. TOTAL	→	2	0	0

G. PREPARED BY (b) (6)	H. DATE	I. APPROVED BY (b) (6)	J. DATE
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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 110 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.

A. CONTRACT LINE ITEM NO. 0001	B. EXHIBIT A	C. CATEGORY: TDP <input checked="" type="checkbox"/> IM <input type="checkbox"/> OTHER <input type="checkbox"/>
--	------------------------	---

D. SYSTEM/ITEM Therapeutics	E. CONTRACT/PR NO. W15QKN21C	F. CONTRACTOR Regeneron
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1. DATA ITEM NO. A011	2. TITLE OF DATA ITEM Product Development Source Material and Manufacturing Reports	3. SUBTITLE
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4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040	5. CONTRACT REFERENCE SOW	6. REQUIRING OFFICE BARDA
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7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY see remarks	12. DATE OF FIRST SUBMISSION see remarks	14. DISTRIBUTION
8. APP CODE		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION see remarks	

16. REMARKS The contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and location and nature of non-clinical and clinical study sites. The contractor will provide manufacturing reports and manufacturing dose tracking projections/actuals utilizing the "COVID-19 Dose Tracking Templates" or similar, on any contract/agreement that is manufacturing product, including product for clinical trial use. • Awardee will submit Product Development Source Material Report o Within (b) (4) of Agreement award o Within (b) (4) of substantive changes are made to sources and/or materials o Or on the (b) (4) contract anniversary. • Contractor will update the Dose Tracking Template weekly during manufacturing campaigns and daily during response operations (where a Public Health Emergency has been declared) and COVID-19 response, with the first deliverable submission within (b) (4) (b) (4) of award/modification. Updates to be provided weekly in advance of commercial-scale manufacturing and daily once material for use in response operations begins manufacture. • The Government will provide written comments to the Product Development Source Material and Manufacturing Report within (b) (4) after the submission • If corrective action is recommended, contractor must address all concerns raised by BARDA in writing • Product Development and Source Material report to be submitted via spreadsheet; Dose Tracking can be completed via spreadsheet or other format (e.g. XML or JSON) as agreed to by USG and company.	a. ADDRESSEE	b. COPIES		
	BARDA	Draft	Final	
	JPEO CBRND	1	Reg	Repro
15. TOTAL	2	0	0	

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

G. PREPARED BY (b) (6)	H. DATE	I. APPROVED BY (b) (6)	J. DATE
----------------------------------	----------------	----------------------------------	----------------

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

A. CONTRACT LINE ITEM NO. 0001	B. EXHIBIT A	C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____
D. SYSTEM/ITEM Therapeutics	E. CONTRACT/PR NO. W15QKN21C	F. CONTRACTOR Regeneron

16. REMARKS *(Continued)*

Agreements Officer or the Agreements Officer's Representative as necessary.

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

Reports for critical items should include the following information:

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

The AO and AOR reserve the right to request un-redacted copies of technical documents provided in response to this subsection, during the period of performance, for distribution within the Government.

Documents shall be provided within (b) (4) after AO issues the request. The contractor may arrange for additional time if deemed necessary, and agreed to by the AO. The Government will have Limited Rights in any documents provided under this subsection.

- Delivery of plan is within (b) (4) of award

CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 110 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.

A. CONTRACT LINE ITEM NO. 0001	B. EXHIBIT A	C. CATEGORY: TDP _____ IM _____ OTHER <u>Regulatory documents</u>
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D. SYSTEM/ITEM Therapeutics	E. CONTRACT/PR NO. W15QKN21C	F. CONTRACTOR Regeneron
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1. DATA ITEM NO. A029	2. TITLE OF DATA ITEM Provision of Public Law 115-92 Sponsor Authorization Letter	3. SUBTITLE
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4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040	5. CONTRACT REFERENCE SOW	6. REQUIRING OFFICE BARDA
--	-------------------------------------	-------------------------------------

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY see remarks	12. DATE OF FIRST SUBMISSION see remarks	14. DISTRIBUTION		
8. APP CODE		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION see remarks	a. ADDRESSEE	b. COPIES	
					Draft	Final

16. REMARKS The Awardee shall submit Public Law 115-92 Sponsor Authorization Letter in the Contractor's format that will be delivered to the designated OWS POC(s). • Within (b) (4) of award	BARDA	1			
	JPEO CBRND	1			
	15. TOTAL	→	2	0	0

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

G. PREPARED BY (b) (6)	H. DATE	I. APPROVED BY (b) (6)	J. DATE
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INSTRUCTIONS FOR COMPLETING DD FORM 1423

(See DoD 5010.12 M for detailed instructions.)

FOR GOVERNMENT PERSONNEL

- Item A.** Self-explanatory.
- Item B.** Self explanatory.
- Item C.** Mark (X) appropriate category: TDP - Technical Data Package; TM - Technical Manual; Other - other category of data, such as "Provisioning," "Configuration Management," etc.
- Item D.** Enter name of system/item being acquired that data will support.
- Item E.** Self-explanatory (to be filled in after contract award).
- Item F.** Self-explanatory (to be filled in after contract award).
- Item G.** Signature of preparer of CDRL.
- Item H.** Date CDRL was prepared.
- Item I.** Signature of CDRL approval authority.
- Item J.** Date CDRL was approved.
- Item 1.** See DoD FAR Supplement Subpart 4.71 for proper numbering.
- Item 2.** Enter title as it appears on data acquisition document cited in Item 4.
- Item 3.** Enter subtitle of data item for further definition of data item (optional entry).
- Item 4.** 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.
- Item 5.** Enter reference to tasking in contract that generates requirement for the data item (e.g., Statement of Work paragraph number).
- Item 6.** Enter technical office responsible for ensuring adequacy of the data item.
- Item 7.** Specify requirement for inspection/acceptance of the data item by the Government.
- Item 8.** Specify requirement for approval of a draft before preparation of the final data item.
- Item 9.** For technical data, specify requirement for contractor to mark the appropriate distribution statement on the data (ref. DoDD 5230.24).
- Item 10.** Specify number of times data items are to be delivered.
- Item 11.** Specify as of date of data item, when applicable.
- Item 12.** Specify when first submittal is required.
- Item 13.** Specify when subsequent submittals are required, when applicable.
- 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 16.** 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.

FOR THE CONTRACTOR

Item 17. Specify appropriate price group from one of the following groups of effort in developing estimated prices for each data item listed on the DD Form 1423.

a. Group I. Definition - Data which is not otherwise essential to the contractor's performance of the primary contracted effort (production, development, testing, and administration) but which is required by DD Form 1423.

Estimated Price - Costs to be included under Group I are those applicable to preparing and assembling the data item in conformance with Government requirements, and the administration and other expenses related to reproducing and delivering such data items to the Government.

b. Group II. Definition - Data which is essential to the performance of the primary contracted effort but the contractor is required to perform additional work to conform to Government requirements with regard to depth of content, format, frequency of submittal, preparation, control, or quality of the data item.

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 Government requirements, and the administrative and other expenses related to reproducing and delivering such data item to the Government.

c. Group III. Definition - Data which the contractor must develop for his internal use in performance of the primary 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 quality of the data item.

Estimated Price - Costs to be included under Group III are the administrative and other expenses related to reproducing and delivering such data item to the Government.

d. Group IV. Definition - Data which is developed by the contractor as part of his normal operating procedures and his effort in supplying these data to the Government is minimal.

Estimated Price - Group IV items should normally be shown on the DD Form 1423 at no cost.

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 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.

DISCLOSURE OF LOBBYING ACTIVITIES

OMB Control Number: 4040-0013

Expiration Date: 2/28/2022

Complete this form to disclose lobbying activities pursuant to 31 U.S.C.1352

1. * Type of Federal Action: <input checked="" type="checkbox"/> a. contract <input type="checkbox"/> b. grant <input type="checkbox"/> c. cooperative agreement <input type="checkbox"/> d. loan <input type="checkbox"/> e. loan guarantee <input type="checkbox"/> f. loan insurance	2. * Status of Federal Action: <input type="checkbox"/> a. bid/offer/application <input checked="" type="checkbox"/> b. initial award <input type="checkbox"/> c. post-award	3. * Report Type: <input checked="" type="checkbox"/> a. initial filing <input type="checkbox"/> b. material change
4. Name and Address of Reporting Entity: <input checked="" type="checkbox"/> Prime <input type="checkbox"/> SubAwardee * Name: <input type="text" value="Regeneron Pharmaceuticals, Inc."/> * Street 1: <input type="text" value="777 Old Saw Mill River Road"/> Street 2: <input type="text"/> * City: <input type="text" value="Tarrytown"/> State: <input type="text" value="NY: New York"/> Zip: <input type="text" value="10591"/> Congressional District, if known: <input type="text" value="4c"/>		
5. If Reporting Entity in No.4 is Subawardee, Enter Name and Address of Prime: <div style="border: 1px solid black; height: 40px;"></div>		
6. * Federal Department/Agency: <input type="text" value="DoD/BARDA"/>	7. * Federal Program Name/Description: <input type="text" value="COVID Therapeutics"/> CFDA Number, if applicable: <input type="text"/>	
8. Federal Action Number, if known: <input type="text" value="Not Applicable"/>	9. Award Amount, if known: \$ <input type="text" value="2,625,000,000.00"/>	
10. a. Name and Address of Lobbying Registrant: Prefix: <input type="text"/> * First Name: <input type="text" value="Not Applicable"/> Middle Name: <input type="text"/> * Last Name: <input style="background-color: yellow;" type="text"/> Suffix: <input type="text"/> * Street 1: <input type="text"/> Street 2: <input type="text"/> * City: <input type="text"/> State: <input type="text"/> Zip: <input type="text"/>		
b. Individual Performing Services (including address if different from No. 10a) Prefix: <input type="text"/> * First Name: <input type="text" value="Not Applicable"/> Middle Name: <input type="text"/> * Last Name: <input style="background-color: yellow;" type="text"/> Suffix: <input type="text"/> * Street 1: <input type="text"/> Street 2: <input type="text"/> * City: <input type="text"/> State: <input type="text"/> Zip: <input type="text"/>		
11. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when the transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Comptroller of the Currency if the total amount of the transaction exceeds \$10,000. If the total amount of the transaction does not exceed \$10,000, the filer the required disclosure shall be subject to a civil penalty of not less than \$10,000. * Signature: <input style="background-color: black; color: red; text-align: center;" type="text"/> (b) (6) * Name: <input style="background-color: black; color: red; text-align: center;" type="text"/> (b) (6) Middle Name: <input type="text"/> Title: <input style="background-color: black; color: red; text-align: center;" type="text"/> (b) (6) Telephone No.: <input type="text"/> Date: <input type="text" value="01/04/2021"/>		
Federal Use Only:		STANDARD FORM LLL (REV. 7/1997) Authorized for Local Reproduction

SMALL BUSINESS SUBCONTRACTING PLAN

(Model Outline* – Template Revised 4/28/2020)

* This template is a **suggested** model for use when formulating a subcontracting plan pursuant to the requirements at FAR 52.219-9(d). While this model plan has been designed to be consistent with FAR 52.219-9, other formats may be acceptable. However, failure to include the essential information as set forth in this model may be cause for either a delay in acceptance or the rejection of an offer where the clause is applicable. Further, the use of this model is not intended to waive other requirements that may be applicable under FAR 52.219-9 or that may appear in the Government's solicitation. "SUBCONTRACT," as used in 52.219-9, **refers to your external company spend**, meaning any agreement (other than one involving an employer-employee relationship) entered into by a federal government prime contractor or subcontractor calling for supplies or services required for performance of the contract or subcontract.

SUBCONTRACTING PLAN PERIOD: January 1, 2021 - December 31, 2021

Individual plans should cover the entire period of performance, and commercial plans should coincide with the company's fiscal year. In the event your company's fiscal year is for a period that will end before the contract periods of any federal contracts you hold which include the requirement to have a small business subcontracting plan, **you will be required to submit a new subcontracting plan for approval thirty (30) days prior to expiration of the existing subcontracting plan.** In the event an acceptable plan cannot be negotiated prior to expiration of the existing subcontracting plan, your contract(s) may be terminated.

DATE SUBMITTED: November 30th 2020

NAME OF PLANHOLDER: Regeneron Pharmaceuticals Inc.

SUBSIDIARIES INCLUDED: (b) (4)

ADDRESS: 777 Old Saw Mill River Road
Tarrytown, NY 10591

ITEM/SERVICE TYPE: Drugs and Pharmaceutical Products

1. TYPE OF PLAN

Select only one of the following plan types (a or b), listing the total estimated dollar value of all planned subcontracting (to all types of business concerns, both large and small). Per 13 CFR 125.3(a)(1)(iii), **the following categories should not be included in the total subcontracting spend base in #1, the proposed goals in #2, nor in the categories of spend listed in #3:** internally generated costs such as salaries and wages; employee insurance; other employee benefits; payments for petty cash; depreciation; interest; income taxes; property taxes; lease payments; bank fees; fines, claims, and dues; Original Equipment Manufacturer relationships during warranty periods (negotiated up front with product); utilities such as electricity, water, sewer, and other services purchased from a municipality or solely authorized by the municipality to provide those services in a particular geographical region; and philanthropic contributions. Utility companies may be eligible for additional exclusions unique to their industry, which may be approved by the contracting officer on a case-by-case basis.

a) **Individual Plan** (This Contract Only) Contract #/Solicitation # _____

Total value of projected subcontracts (both large and small businesses)

Base Period \$ _____ 5-Year Option \$ _____

Total Contract Value (including options) \$ _____

*Separate goals **must** be included for each option period (see #2 and chart on last page)

b) **Commercial Plan** (select one of the following plan types):

Company-wide or **Division-wide**

Total value of projected subcontracts (both large and small businesses) \$ (b) (4)

Total projected sales \$ (b) (4) (Subcontracts Represent (b) (4)% of Total Annual Sales)

State separate dollar and percentage goals, expressed in terms of **percentages of the total available subcontracting dollars** listed in the previous section in #1.

Commercial plans must complete 2a below with 1-year goals, and individual plans must complete 2b below with two separate 5-year goals. Complete only 2a OR 2b, as applicable. Round percentage goals to one decimal place (X.x%).

2a. GOALS FOR COMMERCIAL PLANS (1-Year Goals)

- a) Total estimated dollar value and percent of planned subcontracting with **small businesses (SB)** (including ANCs and Indian tribes), veteran-owned small, service-disabled veteran-owned small, HUBZone small, small disadvantaged (including ANCs and Indian tribes), and women-owned small business concerns: (b) (4)
- b) Total estimated dollar value and percent of planned subcontracting with **veteran-owned small businesses (VO)**: (b) (4)
- c) Total estimated dollar value and percent of planned subcontracting with **service-disabled veteran-owned small businesses (SDVO)** (Note: This is a subset of veteran-owned): (b) (4)
- d) Total estimated dollar value and percent of planned subcontracting with **small disadvantaged businesses (SDB)** (including ANCs and Indian tribes): (b) (4)
- e) Total estimated dollar value and percent of planned subcontracting with **women-owned small businesses (WO)**: (b) (4)
- f) Total estimated dollar value and percent of planned subcontracting with **HUBZone small businesses (HUB)**: (b) (4)

2b. GOALS FOR INDIVIDUAL PLANS (Two, Five-Year Goals)

- a) Total estimated dollar value and percent of planned subcontracting with **small businesses (SB)** (including ANCs and Indian tribes), veteran-owned small, service-disabled veteran-owned small, HUBZone small, small disadvantaged (including ANCs and Indian tribes), and women-owned small business concerns:
Base (5-years): \$____ & ____% & 5-Year Option: \$____ & ____%
- b) Total estimated dollar value and percent of planned subcontracting with **veteran-owned small businesses (VO)**:
Base (5-years): \$____ & ____% & 5-Year Option: \$____ & ____%
- c) Total estimated dollar value and percent of planned subcontracting with **service-disabled veteran-owned small businesses (SDVO)** (Note: This is a subset of veteran-owned):
Base (5-years): \$____ & ____% & 5-Year Option: \$____ & ____%
- d) Total estimated dollar value and percent of planned subcontracting with **small disadvantaged businesses (SDB)** (including ANCs and Indian tribes):
Base (5-years): \$____ & ____% & 5-Year Option: \$____ & ____%
- e) Total estimated dollar value and percent of planned subcontracting with **women-owned small businesses (WO)**:
Base (5-years): \$____ & ____% & 5-Year Option: \$____ & ____%
- f) Total estimated dollar value and percent of planned subcontracting with **HUBZone small businesses (HUB)**:
Base (5-years): \$____ & ____% & 5-Year Option: \$____ & ____%

3. PRODUCTS AND/OR SERVICES

The types of products and/or services to be subcontracted are:

LB: [REDACTED] (b) (4)

SB: [REDACTED] (b) (4)

VO: [REDACTED] (b) (4)

SDVO: [REDACTED] (b) (4)

SDB: [REDACTED] (b) (4)

WO: [REDACTED] (b) (4)

HUB: [REDACTED] (b) (4)

4. GOAL DEVELOPMENT

The following method was used in developing the subcontracting goals:

[REDACTED] (b) (4)

5. IDENTIFYING POTENTIAL SOURCES

The following methods were used to identify potential sources for solicitation purposes (See FAR 52.219-9(d)(5) for examples of methods that may be used.):

[REDACTED] (b) (4)

[REDACTED]

6. INDIRECT COSTS

Indirect costs have have not been included in the dollar and percentage subcontracting goals stated above. (Check one.)

If "have been" is checked (and you are proposing an individual plan), explain the method used in determining the proportionate share of indirect costs to be incurred with small business (including Alaska Native Corporations and Indian tribes), veteran-owned small business, service-disabled veteran-owned small business, small disadvantaged business (including ANCs and Indian tribes), women-owned small business, and HUBZone small business concerns. *Note: Commercial planholders who choose to*

include indirect costs will not need to provide the aforementioned explanation because the costs will be applied at 100%.

7. **PROGRAM ADMINISTRATOR**

The following individual will administer the subcontracting program:

NAME: (b) (6)
TITLE: (b) (6)
ADDRESS: 777 Old Saw Mill River Road
Tarrytown, NY 10591

TELEPHONE: (b) (6)
E-MAIL: (b) (6)

This individual's specific duties, as they relate to the firm's subcontracting program, are as follows: Manage the (b) (4) and administer processes and plans, set goals, develop strategies to achieve stated goals, enhance procedures, monitor the progress of the program and assign responsibilities, guide the sourcing department to assist in the identification of small and diverse suppliers, and prepare and submit the annual eSRS report December 30th and Small Business Subcontract plan November 30th in a timely manner. Act as mentor and provide extensive counseling and advice to small business entities who are interested in participating in sourcing efforts and to those suppliers who were not awarded Regeneron's business after a sourcing event.

In addition, work with Regeneron's legal team to ensure contracts contain all applicable language regarding small business sourcing opportunities. (b) (4)

8. **EQUITABLE OPPORTUNITY**

The following good faith efforts (internal and external) will be taken to assure that small business, veteran-owned small business, service-disabled veteran-owned small business, small disadvantaged business, women-owned small business, and HUBZone small business concerns will have an equitable opportunity to compete for subcontracts:

(b) (4)

[Redacted text block containing multiple lines of blacked-out information]

9. **FLOW-DOWN CLAUSE**

The offeror agrees that the FAR clause of this contract entitled "Utilization of Small Business Concerns" (52.219-8) will be included in all subcontracts that offer further subcontracting opportunities, and that the Offeror will require all subcontractors (except small business concerns) that receive subcontracts in excess of \$700,000 (\$1.5 million for construction of any public facility) with further subcontracting possibilities to adopt a subcontracting plan that complies with the requirements of FAR clause 52.219-9 Small Business Subcontracting Plan.

NOTE: See exceptions listed in FAR 52.219-9(j).

10. **REPORTING & COOPERATION**

The offeror agrees to

- (i) Cooperate in any studies or surveys as may be required;
- (ii) Submit periodic reports so that the Government can determine the extent of compliance by the offeror with the subcontracting plan;
- (iii) After November 30, 2017, include subcontracting data for each order when reporting subcontracting achievements for indefinite-delivery, indefinite-quantity contracts with individual subcontracting plans where the contract is intended for use by multiple agencies;
- (iv) Submit the Individual Subcontract Report (ISR) and/or the Summary Subcontract Report (SSR), in accordance with paragraph (l) of FAR 52.219-9 using the Electronic Subcontracting Reporting System (eSRS) at <http://www.esrs.gov>. The reports shall provide information on subcontract awards to small business concerns (including ANCs and Indian tribes that are not small businesses), veteran-owned small business concerns, service-disabled veteran-owned small business concerns, HUBZone small business concerns, small disadvantaged business concerns (including ANCs and Indian tribes that have not been certified by SBA as small disadvantaged businesses), women-owned small business concerns, and for NASA only, Historically Black Colleges and Universities and Minority Institutions. Reporting shall be in accordance with 52.219-9, or as provided in agency regulations;
- (v) Ensure that its subcontractors with subcontracting plans agree to submit the ISR and/or the SSR using eSRS;
- (vi) Provide its prime contract number, its unique identity identifier, and the e-mail address of the Offeror's official responsible for acknowledging receipt of or rejecting the ISRs, to all first-tier subcontractors with subcontracting plans so they can enter this information into the eSRS when submitting their ISRs; and
- (vii) Require that each subcontractor with a subcontracting plan provide the prime contract number, its own unique identity identifier, and the e-mail address of the subcontractor's official responsible for acknowledging receipt of or rejecting the ISRs, to its subcontractors with subcontracting plans.

11. **RECORDKEEPING**

The following is a description of the types of records that will be maintained concerning procedures that have been adopted to comply with the requirements and goals in the plan, including establishing

source lists; and a description of the offeror's efforts to locate small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns and award subcontracts to them. The records shall include at least the following (on a plant-wide or company-wide basis, unless otherwise indicated):

- (i) Source lists (e.g., SAM), guides, and other data that identify small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns.
- (ii) Organizations contacted in an attempt to locate sources that are small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, or women-owned small business concerns.
- (iii) Records on each subcontract solicitation resulting in an award of more than \$150,000 (**Note: As of the publication of this template, the threshold of \$150,000 has been revised by some agencies via a deviation to either reflect "\$250,000" or to reference "the simplified acquisition threshold" rather than referring to a specific dollar amount.**), indicating—
 - (A) Whether small business concerns were solicited and, if not, why not;
 - (B) Whether veteran-owned small business concerns were solicited and, if not, why not;
 - (C) Whether service-disabled veteran-owned small business concerns were solicited and, if not, why not;
 - (D) Whether HUBZone small business concerns were solicited and, if not, why not;
 - (E) Whether small disadvantaged business concerns were solicited and, if not, why not;
 - (F) Whether women-owned small business concerns were solicited and, if not, why not; and
 - (G) If applicable, the reason award was not made to a small business concern.
- (iv) Records of any outreach efforts to contact—
 - (A) Trade associations;
 - (B) Business development organizations;
 - (C) Conferences and trade fairs to locate small, HUBZone small, small disadvantaged, service-disabled veteran-owned, and women-owned small business sources; and
 - (D) Veterans service organizations.
- (v) Records of internal guidance and encouragement provided to buyers through—
 - (A) Workshops, seminars, training, etc.; and
 - (B) Monitoring performance to evaluate compliance with the program's requirements.
- (vi) On a contract-by-contract basis, records to support award data submitted by the offeror to the Government, including the name, address, and business size of each subcontractor. Contractors having commercial plans need not comply with this requirement.

12 & 13. UTILIZATION OF SMALL BUSINESS CONCERNS USED IN BID/PROPOSAL

12. The offeror agrees to make a good faith effort to acquire articles, equipment, supplies, services, or materials, or obtain the performance of construction work from the small business concerns that it used in preparing the bid or proposal, in the same or greater scope, amount, and quality used in preparing and submitting the bid or proposal. Responding to a request for a quote does not constitute use in preparing a bid or proposal. The Offeror used a small business concern in preparing the bid or proposal if—

- (i) The Offeror identifies the small business concern as a subcontractor in the bid or proposal or associated small business subcontracting plan, to furnish certain supplies or perform a portion of the subcontract; or
- (ii) The Offeror used the small business concern's pricing or cost information or technical expertise in preparing the bid or proposal, where there is written evidence of an intent or understanding that

the small business concern will be awarded a subcontract for the related work if the Offeror is awarded the contract.

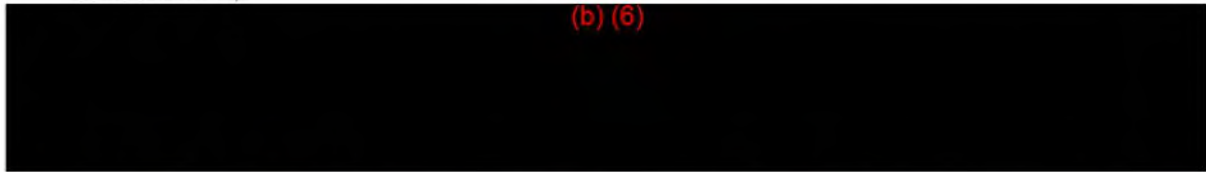
13. The Contractor agrees to provide the Contracting Officer with a written explanation if the Contractor fails to acquire articles, equipment, supplies, services or materials or obtain the performance of construction work as described in (12) above. This written explanation must be submitted to the Contracting Officer within 30 days of contract completion.

14. SUBCONTRACTOR DISCUSSIONS WITH CO

The Contractor agrees not to prohibit a subcontractor from discussing with the Contracting Officer any material matter pertaining to payment to or utilization of a subcontractor.

15. PROMPT PAYMENT OF SMALL BUSINESS SUBCONTRACTORS

The Contractor agrees to pay its small business subcontractors on time and in accordance with the terms and conditions of the underlying subcontract and notify the contracting officer when the prime contractor makes either a reduced or an untimely payment to a small business subcontractor (see FAR 52.242-5).



**Please note that VA FSS will only accept authenticated digital signatures and scanned copies of documents with wet signatures.*

Plan Approval Signature (Government Official)
Typed Name of Government Approver
Date Approved

COMMERCIAL PLANS: SUMMARY OF GOALS

This page is for commercial plans ONLY.

Entries below should match your responses in #1 and #2a at the beginning of the template.

Round percentages to one decimal place (X.x%) and dollar figures to the nearest whole dollar.

	<u>Prior Year Goals</u>	<u>Prior Year Achievements*</u>	<u>Current Goals</u>
1. Total Subcontracting Dollars (both large & small businesses)	\$ (b) (4)	\$ (b) (4)	\$ (b) (4)
2a. Small Business Dollars	\$ (b) (4)	\$ (b) (4)	\$ (b) (4)
SB Percent of Line 1	(b) (4)%	(b) (4)%	(b) (4)%
2b. Small Veteran-owned Dollars	\$ (b) (4)	\$ (b) (4)	\$ (b) (4)
VO Percent of Line 1	(b) (4)%	(b) (4)%	(b) (4)%
2c. Service-Disabled Veteran-Owned Dollars	\$ (b) (4)	\$ (b) (4)	\$ (b) (4)
SDVO Percent of Line 1	(b) (4)%	(b) (4)%	(b) (4)%
2d. Small Disadvantaged Dollars	\$ (b) (4)	\$ (b) (4)	\$ (b) (4)
SDB Percent of Line 1	(b) (4)%	(b) (4)%	(b) (4)%
2e. Small Women-owned Dollars	\$ (b) (4)	\$ (b) (4)	\$ (b) (4)
WO Percent of Line 1	(b) (4)%	(b) (4)%	(b) (4)%
2f. HUBZone Small Business Dollars	\$ (b) (4)	\$ (b) (4)	\$ (b) (4)
HUB Percent of Line 1	(b) (4)%	(b) (4)%	(b) (4)%

** If total prior year contract achievements are not available, use actual figures and estimate/prorate balance. Achievements based on Government's Fiscal Year while Goals are based on Company's Fiscal Year.*

November 30th, 2020

Department of Veterans Affairs
National Acquisition Center (049A1F1)
P.O. Box 76, 1st Avenue North of Cermak Road, Building 37
Hines, IL 60141

To Whom It May Concern,

This letter accompanies our proposal for a Small Business Sub-Contracting Plan ("SBSP"). It is our intention to identify targets for the 2021 fiscal year to reflect realistic and attainable goals for our company. For the purposes of the FY2021 SBSP, Regeneron projects an estimated total value of subcontracts to be [REDACTED] (b) (4)

[REDACTED] (b) (4)

[REDACTED] (b) (4)

As such, Regeneron proposes the following percentage goals for FY 2021:

- Small Business: [REDACTED] (b) (4)%
- Veteran Owned Small Business [REDACTED] (b) (4)%
- Service Disabled Veteran Owned Small Business [REDACTED] (b) (4)%
- Small Disadvantaged Business (SDB) [REDACTED] (b) (4)%
- Small Woman Owned Business [REDACTED] (b) (4)%
- HUB Zone Small Business [REDACTED] (b) (4)%

Please contact me with any questions or comments, that you may have.

Respectfully Submitted,

[REDACTED] (b) (6)

[REDACTED] (b) (4)

SECTION C - PERFORMANCE WORK STATEMENT (PWS)

Manufacturing Quality Engineer Services

C.1 The requiring office for this action is JPM CBRN Medical JPEO CBRND. The Contractor shall not divulge or release information developed or obtained in the course of Contractor performance, except to authorize Government personnel or upon written approval of the Contracting Officer.

C.2 Performance Locations: The Contractor shall provide its efforts at both the Contractor's facility and at Government Facilities in Fort Detrick, MD

C.3 Travel: Contractor travel locations shall include: San Antonio, TX; Boston, MA; Fort Detrick MD

C.4 The Government requires a subject matter expert to provide services necessary to establish an active pharmaceutical ingredient (API) manufacturing capability and support projects with bioprocessing and chemical processing needs, including associated FDA regulated activities. Accordingly, the Contractor shall provide one (1) Manufacturing Quality Engineer to fulfill the requirements below.

C.4.1 The Contractor shall provide input to the Pharmaceutical/Biologics facility design, construction, and qualification of manufacturing facilities, equipment (including controls), quality systems, personnel and bioprocessing and chemical processing needs at JPM Medical.

C.4.2 The Contractor shall review planning documents to identify risk to cost, schedule, and performance and provide input to the Government's Technical Point of Contact (TPOC).

C.4.3 The Contractor shall provide input to project planning and execution and provide input to risk mitigation precautions.

C.4.4 The Contractor shall analyze and provide input to possible risk to cost schedule and performance in the utility systems design, installation, and qualification (HVAC, process gases, water, etc.) plans.

C.4.5 The Contractor shall analyze plans and provide risk mitigation input to potential risk to cost schedule and performance for the cGMP manufacturing processes development, scale-up, tech transfer, and validation stages of the project.

C.4.6 The Contractor shall provide input to the team to establish a compliant Quality Management System (QMS) with an operational quality unit (QA & QC units) to support cGMP manufacturing operations.

C.4.7 The Contractor shall provide input to project schedule, cost estimation and budget management.

C.4.8 The Contractor shall provide input to IPT meeting perspectives as follows:

C.4.8.1 Modular/mobile cGMP manufacturing suite design, installation, and qualification.

C.4.8.2 Continuous manufacturing equipment design, scale-up, installation and

qualification.

C.5 Contractor Manpower Reporting (CMR)

The contractor shall report ALL contractor labor hours (including subcontractor labor hours) required for performance of services provided under this contract via a secure data collection site. The contractor is required to completely fill in all required data fields using the following web address: <http://www.ecmra.mil/> Reporting inputs will be for the labor executed during the period of performance during each Government fiscal year (FY), which runs October 1 through September 30. While inputs may be reported any time during the FY, all data shall be reported no later than October 31 of each calendar year, beginning with 2013. Contractors may direct questions to the help desk at: <http://www.ecmra.mil/>. The required information includes:

(1) Unit Identification Code (UIC) of the Army Requiring Activity that would be performing the mission if not for the contractor: W56XNH.

(2) Command of the Requiring Activity that would be performing the mission if not for the contractor: Medical Countermeasures Systems.

(3) Contracting Officer (KO) and contact information: (b) (6)

(4) Government Technical Point of Contact and contact information: (b) (6)

(5) Federal Service Code (FSC) reflecting services provided by contractor (and separate FSC for each subcontractor if different). If there are multiple FSCs for an Order number, enter a separate data record for each FSC.

(6) Location where contractor and subcontractor(s) perform the service, including the city, state, zip code, and country. When service is performed at an overseas location, state only the city and country. If there are multiple Locations for an Order number, enter a separate data record for each Location. (Note: If there are many location records that need to be entered, the Bulk Loader function is available which allows the transfer of information from a contractor's system to the secure web site. The Bulk Loader Template and Bulk Loader Instructions may be downloaded from the web site.) (7) Contractor Type Prime.

(8) Direct labor hours (including subcontractors) for each FSC.

(9) Direct labor dollars paid this reporting period (including subcontractors) for each FSC.

(10) Weapons system support indication: NO.

If subcontractors are used in the performance of this contract, several factors must be considered. Contractor shall include, and require inclusion of, this term in all subcontracts at any tier under the contract in which services are being procured. Contractor shall also enter their data in a timely manner, as subcontractors cannot input any information into the eCMRA system until the Prime Contractor has entered their data. The Prime Contractor has overall responsibility for ensuring subcontractors enter their respective data. Subcontractors are only responsible for entering Location Data.

C.6 Deliverables

C.6.1 The Contractor shall submit (b) (4) Reports in accordance with Exhibit A, DD1423.

The Contractor shall submit the written report electronically to the Government's TPOC and shall include a detailed list of work accomplished. This list shall include updates on tasks in progress, and completed; updates on any study related problems/issues; and updates on problems/issues identified in previous reporting period. A telephonic meeting will be conducted after receipt to discuss progress and any issues identified.

C.6.2 The Contractor shall submit the Final Report in accordance with Exhibit A, DD1423.

The Contractor shall submit a final report which shall contain in detail the project objectives, work performed, results obtained, and estimates of technical feasibility. A completed SF 298, "Report Documentation Page", shall be used as the first page of the report. (The Report Documentation Page may be prepared and printed from the DoD Electronic Submission Web Site http://www.dtic.mil/dtic/submit/guidance_on_submitting_docs_to_dtic.html.)

(1) For each report, the company submitting the report should fill in block 12 with the following statement: "Distribution authorized to U.S. Government Agencies and their contractors only; Proprietary Information, (Date when completed). Other requests for this document shall be referred to the Technical Point of Contact's Office."

(2) Block 14 (Abstract) of the SF 298, "Report Documentation Page," must include as the first sentence, "Report developed under JPM CBRN Medical contract for Subject Matter Expertise in Manufacturing Capabilities. The abstract must identify the purpose of the work and briefly describe the work carried out, the findings or results and recommendations for future efforts. Since the abstract will be published by the DoD, it must not contain any proprietary or classified data and type "UU" in Block 17.

(3) Block 15 (Subject Terms) of the SF 298 must include the terms "Final Technical Report".

Submission: In accordance with DoD Instruction 3200.12 and DFARS clause 252.235-7011, a copy of the final report shall be submitted (electronically or on disc) to DTIC:

Defense Technical Information Center
ATTN: DTIC-OA
8725 John J Kingman Road, Suite 0944
Ft. Belvoir, VA 22060-6218

C.6.3 The Contractor shall attend a weekly Technical Exchange Meeting Conference call with the Contracting Officer's Representative (COR) Government's Technical Point of Contact (TPOC) in accordance with Exhibit A, DD1423.

The Contractor shall attend a weekly Technical Exchange Meeting Conference call with the COR and Government's TPOC and shall discuss a detailed list of work accomplished for the week NLT 1500 each Friday. This list shall include updates on tasks in progress, and completed; updates on any study related problems/issues; and updates on problems/issues identified in previous reporting period.

QUALITY ASSURANCE SURVEILLANCE PLAN (QASP)

Applicable for the

*Manufacturer Quality Engineer
Subject Matter Expert in Chemistry Manufacturing and Controls
W911QY-21-R-0006*

**U.S. Army Contracting Command - Aberdeen Proving Ground, Natick
Contracting Division**

Written By:

(b) (6)

Chief Technical Officer, JPM CBRN Medical JPEO CBRND

(b) (6)

Reviewed By:


(b) (6)

Contract Support Analyst II

US Army Contracting Command, Aberdeen Proving Ground - Natick Contracting
Division, Fort Detrick Branch

(b) (6)

Approved By:

 Recoverable Signature
X (b) (6)

1.0 INTRODUCTION

This Quality Assurance Surveillance Plan (QASP) is pursuant to the requirements listed in the performance work statement (PWS) for a Subject Matter Expert in chemistry manufacturing and controls. This performance-based plan sets forth the procedures and guidelines the Army Research Laboratory (ARL) will use in evaluating the technical performance of the Contractor.

1.1 PURPOSE

The role of the Government in quality assurance (QA) is to ensure contract standards are achieved. The purpose of the QASP is to identify the methods and procedures the Government will use to evaluate Contractor actions while performing the requirements in the PWS. It is designed to provide an effective surveillance method by monitoring Contractor performance for each listed performance objective in the Performance Requirements Summary (Section 4.0)

1.2 AUTHORITY

Authority for issuance of this QASP is provided under Contract Section E – Inspection and Acceptance, which provides for inspections and acceptance of the articles, services, and documentation called for in task orders to be accomplished by the Contracting Officer or his duly authorized representative. Authority from the FAR can be found at FAR 37.604, FAR 46.401, and DFARS 246.401.

1.3 SCOPE

To fully understand the roles and the responsibilities of the parties, it is important to first define the distinction in terminology between the Quality *Control* Plan and the Quality *Assurance Surveillance* Plan. The Contractor, and not the Government, is responsible for management and quality control actions necessary to meet the quality standards set forth by the contract and follow-on task orders. The Contractor develops and submits (if requested) his Quality Control Plan (QCP) for Government approval in compliance with his contract deliverables. Once accepted, the Contractor then uses the QCP to guide and to rigorously document the implementation of the required management and quality control actions to achieve the specified results. The QASP on the other hand, is put in place to provide Government *surveillance* oversight of the Contractor's quality control efforts to *assure* that they are timely, effective and are delivering the results specified in the contract or task order. The QASP is not a part of the contract nor is it intended to duplicate the Contractor's QCP. The Government may provide the Contractor an information copy of the QASP as an Attachment to the solicitation to support the Contractor's efforts in developing a QCP that will interrelate with the Government's QASP. The QASP has been developed by the requiring activity. It is designed to provide direction to personnel performing contract surveillance activities. Personnel surveying contract terms and conditions and SOW requirements will periodically review the QASP throughout the live of the contract.

2.0. ROLES AND RESPONSIBILITIES

2.1 GOVERNMENT ROLES

The following definitions for Government resources are applicable to this plan:

2.1.1 Contracting Officer - A person duly appointed with the authority to enter into, administer, or terminate contracts and make related determinations and findings on behalf of the Government.

2.1.2 Contracting Officer's Representative (COR) - An individual designated in writing by the Contracting Officer to act as his authorized representative to assist in administering a contract. The source and authority for a COR is the Contracting Officer. COR limitations are contained in the written letter of designation.

2.1.3 Technical Monitor (TM) - An individual designated in writing by the Contracting Officer to act as support to the COR in monitoring contractor performance and completion of the contract. The source and authority for a TM is the Contracting Officer. TM limitations are contained in the written letter of designation.

2.2 RESPONSIBILITIES

The Government resources shall have responsibilities for the implementation of this QASP as follows:

2.2.1 Contracting Officer – The Contracting Officer ensures performance of all necessary actions for effective contracting, ensures compliance with the terms of the contract and safeguards the interests of the United States in the contractual relationship. It is the Contracting Officer that assures the Contractor receives impartial, fair, and equitable treatment under the contract. The Contracting Officer is ultimately responsible for the final determination of the adequacy of the Contractor's performance.

2.2.2 COR - The COR is responsible for technical administration of the project and assures proper Government surveillance of the Contractor's performance. The COR is not empowered to make any contractual commitments or to authorize any contractual changes on the Government's behalf. Any changes that the Contractor deems may affect contract, price, terms, or conditions shall be referred to the Contracting Officer for action.

2.2.3 TM – The TM is responsible for verifying that the Contractor performs the technical requirements of the contract in accordance with the contract terms, conditions and specifications and performs surveillance of the Contractor's performance. The TM is not empowered to make any contractual commitments or to authorize any contractual changes on the Government's behalf. The TM will record and report incidents of faulty or nonconforming work, delays or problems to the COR and the Contracting Officer. In addition, the TM is to submit a monthly report concerning performance of services rendered under this contract to the COR. Any changes that the Contractor deems may affect contract, price, terms, or conditions shall be referred to the Contracting Officer for action.

3.0 METHODS OF QA SURVEILLANCE

The acceptable quality levels (AQL) located in Attachment 1, Required Performance Metrics Table, for contractor performance, are structured to allow the contractor to manage how the work is performed while providing negative incentives for performance shortfalls. All are keyed to the relative importance of the task to the overall mission performance.

3.1 The below listed methods of surveillance shall be used in the administration of this QASP.

3.1.1 Customer Feedback – Customer feedback may be obtained either from the results of formal customer satisfaction surveys or from random customer complaints/suggestions. Customer complaints, to be considered valid, must set forth clearly and in writing the detailed nature of the complaint, must be signed and must be forwarded to the COR. The COR shall maintain a summary log of all formally received customer complaints as well as a copy of each complaint in a documentation file. The COR shall also keep the tabulated results of all customer satisfaction surveys on file.

NOTE: The customer always has the option to communicate complaints to the COR as opposed to the contractor. The COR will accept the customer complaints and will investigate using the Quality Assurance Monitoring Form – Customer Complaint Investigation identified in Attachment III.

3.1.2 100% Inspection - This level of inspection shall be accomplished by inspecting each and every deliverable to the fullest extent practicable. It is preferred for infrequent, low quantity deliverables.

3.1.3 Observation of Performance – The COR will observe the *services* instead of the product or outcome that results.

4.0 PERFORMANCE REQUIREMENTS SUMMARY (PRS)

The following PBSC items are identified within the contract PWS and are to be monitored under this QASP. The related surveillance metrics and performance requirement levels are detailed in Attachment I:

C.6.1 Monthly Reports

C.6.2 Final Technical Report

C.6.3 Weekly Teleconference Calls

4.1 Quality Control Program

The contractor, not the Government, is responsible for management and quality control actions to meet the terms of the contract.

5.0 DOCUMENTATION

The COR will, in addition to providing documentation to the Contracting Officer, maintain a complete QA file. The file will contain copies of all reports, evaluations, recommendations, and any actions related to the Government's performance of the QA

function, including the originals of all completed attachment forms. All such records will be retained for the life of this contract. The COR shall forward these records to the Contracting Officer at termination or completion of the contract, or at Contracting Officer request.

6.0 REVISIONS TO QASP

Revisions to this surveillance plan are the joint responsibility of ARL and the Contracting Officer.

7.0 RATINGS

The evaluation ratings utilized in conjunction with Attachment I are as follows:

7.1 Very Good - Performance meets contractual requirements and exceeds some to the Government's benefit. The contractual performance of the task and sub-task being assessed was accomplished with some minor problems for which corrective actions taken by the contractor were effective.

7.2 Satisfactory - Performance meets contractual requirements. The contractual performance of the task and sub-task contain some minor problems for which corrective actions taken by the contractor appear or were satisfactory.

7.3 Marginal - Performance does not meet some contractual requirements. The contractual performance of the task and sub-task being assessed reflects a serious problem for which the contractor has not yet identified corrective actions. The contractor's proposed actions appear only marginally effective or were not fully implemented.

7.4 Unsatisfactory – Performance does not meet most contractual requirements and recovery is not likely in a timely manner. The contractual performance of the task or sub-task contains a serious problem(s) for which the contractor's corrective actions appear or were ineffective.

8.0 REMEDIES FOR FAILURE TO PERFORM

The contractor may receive deductions or even termination based on failure to perform. The following criteria apply for determining appropriate action:

8.1 Notifications

Consistent with FAR Part 49, the Contracting Officer shall notify the service provider of failure to meet standards through QA monitoring forms, cure notices, or show cause notices and shall inform the service provider project manager or designated alternate of such notices.

8.2 Deductions

The Government has the right to withhold a percentage of payment of the monthly cost for performing particular services based on failure to meet performance standards. The percentage of such withholding is identified in the Required Performance Metrics (RPM) Table of Attachment I.

8.3 Termination

If the Contracting Officer determines that the contractor has failed to perform to the extent that a termination for default is justified, the Contracting Officer shall issue a notice of termination, consistent with FAR Part 49.

9.0 ATTACHMENTS

Attachment I – Required Performance Metrics (RPM) Table

Attachment II – Quality Assurance Monitoring Form

Attachment III – Quality Assurance Monitoring Form – Customer Complaint Investigation

ATTACHMENT I REQUIRED PERFORMANCE METRICS (RPM) TABLE

Required Service	Performance Standards	Acceptable Quality Levels	Method of Surveillance
<i>PRS # 1. Monthly Reports</i> <i>(PWS Para C.6.1)</i>	<i>Monthly Report is thorough, accurate, complete and accepted in accordance with the Data Item Description (DID) if applicable and the SOW.</i> <i>Monthly report shall include a list of meeting</i>	<i>95% accuracy and completeness with first draft.</i> <i>100% accuracy with one correction/rewrite.</i>	<i>100% inspection of deliverables</i>

	<p><i>attended, title, date, and duration</i></p> <p><i>For each meeting the contractor shall note recommendations made to the team</i></p> <p><i>The contractor shall document risks identified during the project for decisions the team is making</i></p>		
<p><i>PRS # 2</i></p> <p><i>Final Report</i></p> <p><i>(PWSPara C.6.2)</i></p>	<p><i>Final Report contains required information and is accurate, complete and accepted in accordance with the Data Item Description (DID) if applicable and the SOW.</i></p> <p><i>The contractor shall provide lessons learned related to the success or failure of the program (incremental and total).</i></p> <p><i>The contractor shall provide a listing of recommendations</i></p>	<p><i>95% accuracy and completeness with first draft.</i></p> <p><i>100% accuracy with one correction/rewrite.</i></p>	<p><i>100% inspection of deliverables</i></p>

	<p>for the program's next steps.</p> <p>The contractor shall provide a risk assessment of key decisions made in the program. Key decisions will be discussed between the COR and the contractor prior to the assessment (2 weeks).</p>		
<p>PRS # 3</p> <p>Weekly Technical Exchange Meeting</p> <p>(PWSPara C.6.3)</p>	<p><i>The Weekly Technical Exchange Meeting shall include shall discuss a detailed list of work accomplished for the week NLT 1500 each Friday.</i></p> <p><i>This list shall include updates on tasks in progress, and completed; updates on any study related problems/issues; and updates on problems/issues identified in</i></p>	<p>95% accuracy and completeness with first draft.</p> <p>100% accuracy with one correction/rewrite.</p>	<p>100% inspection of deliverables</p>

	<p><i>previous reporting period. a list of meeting attended, title, date, and duration</i></p> <p><i>For each meeting the contractor shall note recommendations made to the team.</i></p> <p><i>The contractor shall document risks identified during the project for decisions the team is making.</i></p>		
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PREPARED BY: _____

DATE:

ATTACHMENT III

**QUALITY ASSURANCE MONITORING FORM –
CUSTOMER COMPLAINT INVESTIGATION**

SERVICE or STANDARD:

SURVEY PERIOD: _____

DATE/TIME COMPLAINT RECEIVED: _____ AM / PM

SOURCE OF COMPLAINT: _____ (NAME)

_____ (ORGANIZATION)

_____ (PHONE NUMBER)

_____ (EMAIL ADDRESS)

NATURE OF COMPLAINT:

RESULTS OF COMPLAINT INVESTIGATION:

DATE/TIME SERVICE PROVIDER INFORMED OF COMPLAINT: _____
_____ AM / PM

CORRECTIVE ACTION TAKEN BY SERVICE PROVIDER:

RECEIVED AND VALIDATED BY: _____

PREPARED BY: _____

DATE:

INSTRUCTIONS FOR COMPLETING DD FORM 1423

(See DoD 5010.12-M for detailed instructions.)

FOR GOVERNMENT PERSONNEL

- Item A.** Self-explanatory.
- Item B.** Self-explanatory.
- Item C.** Mark (X) appropriate category: TDP - Technical Data Package; TM - Technical Manual; Other - other category of data, such as "Provisioning," "Configuration Management," etc.
- Item D.** Enter name of system/item being acquired that data will support.
- Item E.** Self-explanatory (to be filled in after contract award).
- Item F.** Self-explanatory (to be filled in after contract award).
- Item G.** Signature of preparer of CDRL.
- Item H.** Date CDRL was prepared.
- Item I.** Signature of CDRL approval authority.
- Item J.** Date CDRL was approved.
- Item 1.** See DoD FAR Supplement Subpart 4.71 for proper numbering.
- Item 2.** Enter title as it appears on data acquisition document cited in Item 4.
- Item 3.** Enter subtitle of data item for further definition of data item (optional entry).
- Item 4.** 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.
- Item 5.** Enter reference to tasking in contract that generates requirement for the data item (e.g., Statement of Work paragraph number).
- Item 6.** Enter technical office responsible for ensuring adequacy of the data item.
- Item 7.** Specify requirement for inspection/acceptance of the data item by the Government.
- Item 8.** Specify requirement for approval of a draft before preparation of the final data item.
- Item 9.** For technical data, specify requirement for contractor to mark the appropriate distribution statement on the data (ref. DoDD 5230.24).
- Item 10.** Specify number of times data items are to be delivered.
- Item 11.** Specify as-of date of data item, when applicable.
- Item 12.** Specify when first submittal is required.
- Item 13.** Specify when subsequent submittals are required, when applicable.
- 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 16.** 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.

FOR THE CONTRACTOR

Item 17. Specify appropriate price group from one of the following groups of effort in developing estimated prices for each data item listed on the DD Form 1423.

a. Group I. Definition - Data which is not otherwise essential to the contractor's performance of the primary contracted effort (production, development, testing, and administration) but which is required by DD Form 1423.

Estimated Price - Costs to be included under Group I are those applicable to preparing and assembling the data item in conformance with Government requirements, and the administration and other expenses related to reproducing and delivering such data items to the Government.

b. Group II. Definition - Data which is essential to the performance of the primary contracted effort but the contractor is required to perform additional work to conform to Government requirements with regard to depth of content, format, frequency of submittal, preparation, control, or quality of the data item.

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 Government requirements, and the administrative and other expenses related to reproducing and delivering such data item to the Government.

c. Group III. Definition - Data which the contractor must develop for his internal use in performance of the primary 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 quality of the data item.

Estimated Price - Costs to be included under Group III are the administrative and other expenses related to reproducing and delivering such data item to the Government.

d. Group IV. Definition - Data which is developed by the contractor as part of his normal operating procedures and his effort in supplying these data to the Government is minimal.

Estimated Price - Group IV items should normally be shown on the DD Form 1423 at no cost.

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 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.