

AWARD/CONTRACT		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)			RATING	PAGE OF PAGES 1 22	
2. CONTRACT (Proc. Inst. Ident.) NO. W911SR2030005		3. EFFECTIVE DATE 11 Jul 2020		4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 0011506627-0001			
5. ISSUED BY USA CONTRACTING CMD-APG - W911SR EDGEWOOD CONTRACTING DIVISION 8456 BRIGADE STREET BLDG E4215 ABERDEEN PROVING GROUND MD 21010-5401		CODE W911SR	6. ADMINISTERED BY (If other than Item 5) DCMA TWIN CITIES - S2401A 5600 WEST AMERICAN BOULEVARD, SUITE 600 BLOOMINGTON MN 55111-4080		CODE S2401A		
7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and zip code) SMITHS MEDICAL ASD, INC. 6000 NATHAN LN N PLYMOUTH MN 55442-1690				8. DELIVERY [] FOB ORIGIN [X] OTHER (See below)			
				9. DISCOUNT FOR PROMPT PAYMENT NET 30 Days			
				10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN: ITEM			
CODE 52087		FACILITY CODE		12. PAYMENT WILL BE MADE BY DFAS-COLUMBUS CENTER DFAS-COMWEST ENTITLEMENT OPERATIONS P.O. BOX 182381 COLUMBUS OH 43218-2381			
11. SHIP TO/MARK FOR BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT (b) (6) (b) (6) O'NEILL HOUSE OFFICE BUILDING WASHINGTON DC 20515		CODE W56XNH	CODE HQ0339				
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: [] 10 U.S.C. 2304(c)() [] 41 U.S.C. 253(c)()			14. ACCOUNTING AND APPROPRIATION DATA See Schedule				
15A. ITEM NO.	15B. SUPPLIES/ SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT		
SEE SCHEDULE							
15G. TOTAL AMOUNT OF CONTRACT					\$20,663,774.00		
16. TABLE OF CONTENTS							
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CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE							
17. [] CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)				18. [] SEALED-BID AWARD (Contractor is not required to sign this document.) Your bid on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the terms listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)			
19A. NAME AND TITLE OF SIGNER (Type or print) (b) (6)				20A. NAME OF CONTRACTING OFFICER TEL: _____ EMAIL: _____			
19B. NAME OF CONTRACTOR (b) (6)		19C. DATE SIGNED 11 JUL 2020		20B. UNITE (b) (6) BY _____ (Signature of Contracting Officer)		20C. DATE SIGNED	

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	TECHNOLOGY INVESTMENT AGREEMENT COST TECHNOLOGY INVESTMENT AGREEMENT for Expanding Domestic Production of Needles & Syringes IAW vendor project plan dated 30 June 2020. FOB: Destination PURCHASE REQUEST NUMBER: 0011506627-0001 PSC CD: 6615		Job		\$20,663,774.00 NTE
	ACRN AA CIN: GFEBS001150662700001			ESTIMATED COST	\$20,663,774.00 \$20,663,774.00

Section E - Inspection and Acceptance

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Destination	Government	Destination	Government

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
0001	POP 11-JUL-2020 TO 11-JUL-2028	N/A	BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT (b) (6) (b) (6) O'NEILL HOUSE OFFICE BUILDING WASHINGTON DC 20515 FOB: Destination	W56XNH

Section G - Contract Administration Data

ACCOUNTING AND APPROPRIATION DATA

AA: 0212020202120400000664643255 S.0074658.5.1 6100.9000021001
COST CODE: A5XAH
AMOUNT: \$20,663,774.00

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	0001	GFEB001150662700001	\$20,663,774.00

Section H - Special Contract Requirements

SPECIAL REQUIREMENTS

H.1 Key Personnel

H.1.1 Pursuant to HHSAR 352.237-75 (Dec 2015), Key Personnel, any key personnel specified in this contract are considered to be essential to work performance. At least thirty (30) calendar days prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer 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 thirty (30) calendar-day notice, 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 Contracting Officer. 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:

H.1.2 Substitution of Key Personnel

H.1.2.1 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.

H.1.2.2 All requests for substitution must provide a detailed explanation of the circumstance necessitating the proposed substitution, a complete resume for the proposed substitute and any other information requested by the contracting officer to approve or disapprove the proposed substitution. All proposed substitutes must have qualifications that are equal to or higher than the qualifications of the person to be replaced. The contracting officer or authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.

H.1.2.3 The contractor further agrees to include the substance of this clause in any subcontract, which may be awarded under this contract.

H.2 Disclosure of Information:

H.2.1 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 developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO. 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.

H.2.2 Consistent with HHS Directive 1139, the Contractor shall comply with HHS requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the HHS's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

H.2.3 No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing

or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

H.3 PUBLICATION AND PUBLICITY

H.3.1 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, for additional information see HHSAR 352.227-70. Publications and Publicity (Dec 2015).

(a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published.

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

(c) The contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies HHS 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 Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Agreement No. W911SR2030005."

H.4 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 Agreements Officer and the Contractor may, by mutual consent, identify elsewhere in this agreement 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 Agreements Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the agreement. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this agreement that information to be utilized under this agreement, or a portion thereof, is subject to the Privacy Act, the 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 agreement, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions

of this article, the Contractor shall obtain a written determination from the Agreements Officer prior to any release, disclosure, dissemination, or publication.

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

g. The provisions of 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.

H.5 Organizational Conflicts of Interest:

H.5.1 Performance under this agreement 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 agreement, 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 agreement, upon determination that an OCI has occurred.

H.5.2 The work performed under this agreement 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 Contractor's performance of this agreement, 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.

H.5.3 The Contractor shall notify the Agreements Officer 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 Agreements Officer to either avoid or mitigate any such OCI. The Agreements Officer will have sole discretion in accepting the Contractor's mitigation plan. In the event the Agreements Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the Contractor from participating in agreement requirements related to OCI.

H.5.4 Whenever performance of this agreement provides access to another Contractor's proprietary information, the Contractor shall:

(1) 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, for example to provide assistance during technical evaluation of other Contractors' offers or products under this agreement. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the CO within fifteen (15) calendar days of execution.

H.6 Operations Security (OPSEC)

H.6.1 The contractor shall develop and submit an OPSEC Standing Operating Procedure (SOP)/Plan within 30 calendar days of agreement award, to be reviewed and approved by the Government OPSEC lead for this effort. The final OPSEC plan, must address the Government's identified Critical Information List (CIL)

a) All contractors supporting this effort must complete OPSEC Computer Based Training (CBT) that can be accessed via the (Insert applicable website here).

H.7 BARDA Security Requirements—SOP Attachment D

H.7.1 The Recipient shall provide a report containing a gap analysis of Recipient's security capabilities against the BARDA Security Requirements specified below ("Gap Analysis Report"). The Recipient's plan shall be delivered to the Government within 30 days of award. The Recipient shall request the same gap analysis from all subcontractors, consultants, researchers, etc. performing work on behalf of this effort, against the Final Security Plan, or shall notify BARDA of any deficiencies contained in such subcontractors, consultants, researchers, etc. capabilities ("Subcontractor Gap Analysis Report").

- a) BARDA will review in detail and submit comments on the Gap Analysis Report or a Subcontractor Gap Analysis Report within ten (10) business days to the Agreements Officer (AO) to be forwarded to the Recipient. The Recipient shall review BARDA's comments and, submit a final security plan to the Government within thirty (10) calendar days after receipt of the comments. Government shall reimburse Recipient for any and all additional measures that Recipient must take to comply with BARDA's comments.
- b) The Final Security Plan shall include a timeline for compliance of all the required security measures outlined by BARDA.
- c) Upon completion of initiating all security measures, the Contractor shall supply to the Agreements Officer a letter certifying compliance to the elements outlined in the Final Security Plan.

Section I - Contract Clauses

TERMS & CONDITIONS

TECHNOLOGY INVESTMENT AGREEMENT

between

Smiths Medical ASD, Inc.

and

**Department of Defense,
U.S. Army Contracting Command –Aberdeen Proving Ground,
Natick Contracting Division &Edgewood Contracting Division
(ACC-APG-NCD & ECD)**

on behalf of

Biomedical Advanced Research and Development Authority (BARDA)

for the

Expanding Domestic Production of Needles & Syringes

Agreement No.:W911SR-20-3-0005

Total Amount of Government Funding for the Agreement: \$20,663,774

Total Cost Share for the Agreement: \$16,542,028

Total Estimated Value of the Agreement: \$37,205,802

Effective Date: 11 July 2020

TECHNOLOGY INVESTMENT AGREEMENT TERMS AND CONDITIONS

ARTICLES

1. Scope of Agreement
2. Term of Agreement
3. Order of Precedence
4. Program/Administrative Management
5. Financial Management & Payment
6. Accounting & Audit
7. Purchasing & Title
8. Cost Sharing
9. Government Preference
10. Records Retention & Government Access
11. Intellectual Property & Patent Rights
12. Data Rights
13. FDA Regulatory Requirements
14. Termination
15. Disputes
16. Reports & Distribution
17. Modification
18. Miscellaneous

ATTACHMENTS

- A. Recipient's Proposal (Final Project Plan dated 30 June 2020)
 - B. Collaboration Plan (Statement of Objectives [SOO] dated 28 May 2020)
 - C. Gantt Chart
 - D. BARDA Security SOP
 - E. PDF version of the RFFP Financials v4
 - F. Direct Labor Cost
 - H. BARDA Program Management Org Chart
 - I. CV's associated with BARDA Program Management Org Chart
- Exhibit: Smiths – Marathon Amendment, dated 10 July 2020

RECITALS

This Agreement is entered into between the United States of America, Department of Defense, represented by ACC-APG-NCD (“Government”) and Smiths Medical ASD, Inc., (“Recipient”), collectively referred to as the “Parties,” pursuant to and under the statutory authority at 10 U.S.C. §2371 and/or 10 U.S.C. §2358.

The Recipient, a for-profit firm, submitted a basic, applied, or advanced research proposal to the Government in response to the publicly disseminated Medical Countermeasures System (MCS) Broad Agency Announcement (BAA) 17-01. The proposal was identified within the MCS BAA scope of: Advanced Development & Manufacturing Capabilities (ADMC), to develop a national capability and capacity to develop and produce medical countermeasures rapidly to counter known or unknown chemical, biological, radioactive, and nuclear (CBRN) threats, including novel and previously unrecognized, naturally- occurring emerging infectious diseases such as the COVID-19 virus. The specific MSC BAA Area of Interest is Mission Area 1, Medical Biological Prophylaxis.

The Government awards this Technology Investment Agreement (TIA) to fund the Recipient proposal subject to the following terms and conditions and other statutory requirements. The Parties desire to enter into this Agreement to establish said terms and conditions under which they plan to carry out the research and other activities as described below.

THEREFORE, THE PARTIES AGREE:

1. Scope of Agreement

1.1 Governing Authority

This Technology Investment Agreement (TIA) is an assistance transaction other than a grant or cooperative agreement and is awarded pursuant to 10 USC §2371 and/or 10 USC §2358, as applicable, as implemented by 32 Code of Federal Regulations (CFR) Part 37, and Parts 22 and 34 where specifically referenced. The following are also incorporated in full: Definitions at Subpart J of 32 CFR Part 37; National Policies at Appendix B, 32 CFR Part 22; Audits at Appendix C of 32 CFR Part 37. This TIA is subject to 21 CFR 820, as applicable. The Federal Acquisition Regulation (FAR), Defense Federal Acquisition Regulation Supplement (DFARS), DoD Grant and Agreement Regulations (DoDGARs), or other regulatory and statutory requirements apply as specifically referenced herein. If this instrument is awarded under the authority at 10 USC §2358, the Bayh-Dole Act, 35 U.S.C. §§ 200-212 applies, as applicable.

1.2 Principle Purpose

The Government and the Recipient agree that the principle purpose of this Agreement is for Government investment into the expansion of Recipient’s existing Domestic Production of Needles & Syringes capacities to support research efforts in pursuit of domestic development and distribution of a vaccine in response to the worldwide COVID-19 pandemic as described in Smiths Medical proposal entitled “BARDA/SMITH Medical – Hypodermic Additional Capacity Proposal”, dated 30 June 2020, hereinafter, the “Plan” or “Project”. This effort shall be carried out as set forth in the Recipient’s Proposal and subsequent revisions, which are hereby incorporated in their entirety. This Agreement is not intended to be, nor shall it be construed as, by implication or otherwise, a partnership, a corporation, or other business organization.

2. Term of Agreement

This Agreement shall commence upon the effective date listed on page 1, after execution of the Agreement by both parties, for a period of (b) (4), the “term” of the Agreement or “Period of Performance.” *Period of performance* means the time during which a recipient or subrecipient may incur new obligations to carry out the work authorized under an award or subaward, respectively.

3. Order of Precedence

This Agreement is subject to the laws and regulations of the United States. In the event of a conflict or

inconsistency in the terms and conditions or attachments specified in this Agreement, the conflict or inconsistency shall be resolved according to the following order of precedence: (a) the Federal statute authorizing this award, or any other Federal statutes directly affecting performance of this Agreement, including attachments where applicable; (b) Federal regulations specifically references; (c) the terms and conditions contained within the Agreement, including any documents incorporated; (d) programmatic requirements.

4. Program/Administrative Management

4.1 Program Management

The Recipient has full responsibility for the project/activity supported by this Agreement, in accordance with the Recipient's proposal and proposal revisions/appendices, and the terms and conditions specified in this Agreement. The Government will have continuous and/or substantial involvement with the Recipient pursuant to a Collaboration Plan as incorporated. The Recipient must consult the Program Office /Technical Representative through the Agreement Officer before deviating from the objectives or overall program of the research originally proposed. Non-compliance with any award provision of this clause may result in the withholding of funds and or the termination of the award.

4.2 Government Representatives:

Agreements Officer (AO)

(b) (6)

ACC-APG-NCD

1 General Greene Avenue

Natick, Ma 01760

(b) (6)

Agreements Specialist (AS)

(b) (6)

ACC-APG-ECD

8456 Brigade Street

Building E4215

APG, MD 21010-5401

(b) (6)

Administrative Grants Officer (AGO)

DCMA Twin Cities

5600 West American Boulevard, Suite 600

Bloomington, MN 55111-4080

dcma.lee.hq.list.s2401a-casd@mail.mil

BARDA Program Manager

(b) (6)

Biomedical Advanced Research and Development Authority

Assistant Secretary for Preparedness and Response

Department of Health and Human Services

Washington, DC

(b) (6)

4.3 Recipients Representatives

(b) (6)

Smiths Medical
6000 Nathan Lane North.
Minneapolis, MN, 55442

(b) (6)

5. Financial Management & Payment

5.1 Expenditure-Based.

This Agreement is an expenditure type Technology Investment Agreement (TIA) as described in 32 CFR §37.1285. Expenditure is defined in 32 CFR§ 37.1290. *Expenditures* mean charges made by a recipient or sub-recipient to a project or program under an award. The charges may be reported on a cash or accrual basis, as long as the methodology is disclosed and is consistently applied. In accordance with 32 CFR 37.300(a) "For an expenditure-based TIA, the amounts of interim payments or the total amount ultimately paid to the recipient are based on the amounts the recipient expends on project costs. If a recipient completes the project specified at the time of award before it expends all of the agreed-upon Federal funding and recipient cost sharing, the Federal Government may recover its share of the unexpended balance of funds or, by mutual agreement with the recipient, amend the agreement to expand the scope of the research project. An expenditure-based TIA therefore is analogous to a cost-type procurement contract or grant."

Payments shall be made on a monthly basis for expenditures incurred up to the agreed upon project ceiling & Government investment funding amount, for the duration of the Period of Performance & in accordance with the Project Plan.

5.2 Obligation

In no case shall the Government's financial obligation exceed the amount obligated on this Agreement or by amendment to the Agreement. The Government is not obligated to reimburse the Recipient for expenditures in excess of the amount of obligated funds allotted by the Government.

5.3 Wide Area Workflow. The following guidance is provided for invoicing processed under this Agreement through WAWF:

5.3.1. Acceptance within the WAWF system shall be performed by the AGO upon receipt of a confirmation email, or other form of transmittal, from the BARDA PM.

5.3.2. The Recipient shall send an email notice to the BARDA PM and upload the BARDA PM approval as an attachment upon submission of an invoice in WAWF (this can be done from within WAWF).

5.3.3. Payments shall be made by the Defense Finance and Accounting Services (DFAS) office indicated below within thirty (30) calendar days of an accepted invoice in WAWF:

Defense Finance and Accounting Service (DFAS)

DFAS COLUMBUS- WEST Entitlement Operations
P.O. Box 182381
Columbus Center
Columbus, OH 43218'2317

1-800-552-7671

5.3.4. WAWF Provision:

(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.

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

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

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

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

(f) WAWF payment instructions. The Recipient must use the following information when submitting payment requests and receiving reports in WAWF for this contract/order:

(1) Document type. The Recipient shall use the following document type:
Invoice and Receiving Report (**Combo**)

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

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

Routing Data Table*

<i>Field Name in WAWF</i>	<i>Data to be entered in WAWF</i>
Pay Official DoDAAC	HQ0339
Issue By DoDAAC	W911SR
Admin DoDAAC	S2401A
Inspect By DoDAAC	W56XNH
Ship To Code	W56XNH

Payee Information: As identified at the System for Award Management.

- Smiths Medical
- Cage Code: 52087
- DUNS: 056329097

(4) Payment request and supporting documentation. The Recipient shall ensure a payment request includes appropriate contract line item and subline item descriptions of the work performed or supplies delivered, unit price/cost per unit, fee (if applicable), and all relevant back-up documentation in support of each payment request.

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

DCMA POC: (b) (6)

(g) WAWF point of contact.

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

Administrative Grants Officer (AGO)
DCMA Twin Cities
5600 West American Boulevard, Suite 600
Bloomington, MN 55111-4080

(b) (6)

- (2) For technical WAWF help, contact the WAWF helpdesk at 866-618-5988.

6. Accounting & Audit

6.1 Accounting System.

6.1.1. The Recipient's systems must demonstrate effective control of all funds. Control systems must be adequate to ensure that costs charged to Federal funds and those counted as the Recipient's cost share or match are consistent with requirements for cost reasonableness, allowability, and allocability in the applicable cost principles as set forth in 32 CFR §37.625(b) and in the terms and conditions of the award. The Recipient must be able to provide accurate, current and complete records that document for each project funded wholly or in part with Federal funds the source and application of the Federal funds and the Recipient's required cost share or match.

6.1.2. The Recipient's cost accounting system shall be in compliance with Generally Accepted Accounting Principles (GAAP) in accordance with 32 CFR §37.615. The system must effectively control all project funds, including Federal funds and any required cost share. The system must have complete, accurate, and current records that document the sources of funds and the purposes for which they are disbursed. It also must have procedures for ensuring that project funds are used only for purposes permitted by the agreement (§ 37.625).

6.2 Annual Audit Requirement.

The Recipient shall have an annual audit performed by the Defense Contract Audit Agency (DCAA), or, an independent auditor, in accordance with 32 CFR §37.650. It is preferable that DCAA conduct the audit if the Recipient will grant DCAA access to information and records required to complete the audit. The Recipient shall provide a copy of the auditor's report to the Agreements Officer within 60 days after audit. Audits at Appendix C of 32 CFR Part 37 is incorporated into this Agreement.

7. Purchasing & Title

7.1 Title to Property Acquired under Agreement. Title to real property, equipment, and supplies or intangible property that are acquired by the Recipient (whether by purchase, construction or fabrication, development, or otherwise) under this award vests in the Recipient. Pursuant to a statutory exception, the Government may allow vesting without further obligation any property or equipment directly charged to the project, for which the Government otherwise retains a Federal interest. If there is a Federal interest in the property, the Government retains this interest throughout the period of performance and/or option periods.

7.2 Disposition. Any Federal interest in the real property or equipment remaining after the term will be addressed at the time of property disposition. Disposition will be in accordance with 32 CFR 34.21.

7.3 Purchasing System. If the Recipient currently performs under DoD assistance instruments subject to the purchasing standards in [32 CFR 34.31](#), then that Part applies. Otherwise, the Recipient may use the existing purchasing systems, as long as applicable requirements are flowed down (37.705).

8. Cost Sharing

8.1 To the maximum extent practicable, the recipient must provide at least half of the costs of the project, in accordance with [§ 37.215](#). *Total value* of the TIA means the total amount of costs that are currently expected to be charged to the award over its life, which includes amounts for the Federal share and any non-Federal cost sharing or matching required under the award; and any options, even if not yet exercised, for which the costs have been established in the award.

8.2 The Government funding is estimated to represent approximately (b) (4) of the overall amount necessary to accomplish the scope of work cited in the proposal (inclusive of all proposal revisions and appendices). The Recipient agrees to provide the resources in the manner shown in their proposal.

8.3 Failure of either Party to provide its respective total contribution may result in a unilateral modification to this Agreement by the Agreements Officer to reflect proportional reduction in funding for the other Party.

9. Government Preference

9.1 Pricing. Recipient agrees that for period of (b) (4) following the completion of Phase II it shall not offer, sell or otherwise provide Products that are produced using the new EDGETM assembly line that will be purchased and implemented by Recipient during Phase II with funds from the Government's investment (the "New

Line”) to any entity (b) (4) the Products from Marathon Medical Corporation. In the event that Recipient provides the above referenced Products produced using the New Line to a third party at a lower unit price than the price Marathon Medical Corporation charges the Government for such Products, Recipient shall promptly notify the OTA0 in writing of the lower price. For purchases made after the completion of Phase II, but prior to provision of the notice contemplated in the preceding sentence, the Recipient shall reimburse the Government, the difference between the lower price provided to the other customer(s) and the price paid by the Government to the Marathon Medical Corporation multiplied by the volume/quantity provided. Such reimbursement shall occur within thirty days (30) of the Recipient discovering that the lower price was given to another customer. Notwithstanding the foregoing, the parties may agree to apply the difference in price paid by the other customer(s) and the price the Government paid to Marathon Medical Corporation for the Products into additional quantities/volume required by the Government.

9.2 Precedence. During the period of performance and for a period of (b) (4) years following the completion of Phase II and upon a Presidential Declaration of a Public Health Emergency (a "PHE"), Recipient shall grant Marathon Medical Corporation the right to place Priority Orders (as defined below) on behalf of the Government for Products using the New Line, so long as the Products are intended for use to address the PHE. Further, Recipient shall cause Marathon Medical Corporation to grant priority to orders for the Products from the Government. For purposes of this Section, (a) "Priority Orders" shall mean purchase orders for Product that will be prioritized by Recipient on the New Line ahead of any unrated order for Product using the New Line.

9.3 Maintenance of equipment and availability of capacity. Recipient agrees that for a period of (b) (4) following the commissioning of the New Line funded by this Agreement, that it shall maintain the New Line in such a way as to ensure that, should the rights established under 9.1 and 9.2 be in effect, there is capacity equal to that which was available at time of commissioning, subject to Recipient's ability to procure raw materials and components used to produce the Products following a reasonable re-qualification period for the New Line. Further, the Recipient agrees that should the New Line funded by this agreement be unavailable during the period referenced above, the Recipient will make available to the Government equivalent capacity from equipment not funded under this agreement.

9.4. Inspection of equipment. The Recipient grants the Government the right to inspect at any time, upon provision of reasonable advance notice, the equipment funded by this agreement. This right shall be in effect for 10 years following commissioning of the equipment.

10. Records Retention & Government Access

The DoD, Comptroller General of the United States, or any of their duly authorized representatives, have the right of timely and unrestricted access to any books, documents, papers, or other records of the Recipient that are pertinent solely to the Recipient's technical performance under this Agreement, in order to make examinations, excerpts, transcripts and copies of such documents. This right also includes timely and reasonable access to the Recipient's personnel for the purpose of interview and discussion related to such records. Such access shall be performed during business hours on business days upon written notice and shall be subject to the security requirements of the audited Party to the extent such security requirements do not conflict with the rights of access otherwise granted by this paragraph. The rights of access in this paragraph shall last for a period of three (3) years after the last payment. The rights of access in this paragraph do not extend to the Recipient's financial records.

11. Intellectual Property & Patent Rights—Not Applicable

12. Data Rights

The Government may only request technical data that is customarily provided to the public: with a commercial item for or process related to Products, equipment purchased under this Agreement, and repairs or

maintenance to said equipment.

13. U.S Food and Drug Administration (FDA) Regulatory Compliance

13.1 Quality System Regulations Compliance. The Recipient will ensure that the manufacturing capability established under this Agreement is fully compliance with current Quality System Regulations under 21 CFR 820. The Recipient will notify the Government of any inspection results from the U.S. Food and Drug Administration (FDA).

13.2 FDA Communications. The Recipient will provide the Government with all communications and summaries thereof to or from the FDA regarding the manufacturing contemplated under this Agreement and ensure that Government representatives are invited to participate in any scheduled meetings with the FDA.

14. Termination

Termination and Enforcement procedures are in accordance with 32 CFR §34.51 through §34.52.

15. Disputes

For any disagreement, claim, or dispute arising under this Agreement, the parties shall communicate with one another in good faith and in a timely and cooperative manner. Whenever disputes, disagreements, or misunderstandings arise, the parties shall attempt to resolve the issue by discussion and mutual agreement as soon as practicable. Failing resolution by mutual agreement, the aggrieved party shall request a resolution in writing from the AO. The AO will review the matter and render a decision in writing. Any such decision is final and binding. In the event of a decision, within (60) calendar days of the referral for review (or such other period as agreed upon by the parties), either party may pursue any right or remedy provided by law in a court of competent jurisdiction as authorized by 28 U.S.C. 1491. Alternately, the parties may agree to explore and establish and Alternate Disputes Resolution (ADR) procedure to resolve this dispute.

16. Reports & Distribution

16.1 Monthly Progress Reports. Submitted monthly no later than the 10th of the month. Recipient format acceptable. Electronic submission acceptable in MS Office or PDF format. Financial information shall be MS Excel format. Monthly reports shall NOT be marked proprietary and shall have Distribution Statement C (U.S. Government and their contractors). Each monthly report shall, at a minimum, contain the following:

- a. Summary of monthly progress for the Recipient's facilities/capabilities associated with this effort
- b. Summary of progress towards established milestones for each facility/capability
- c. Identification of any milestone that is slipping or missed, and discussion of path forward to bring milestone back to schedule, and impact on other milestones
- d. Summary of risks, discussion of potential impacts and efforts to mitigate
- e. Summary of overall schedule and changes from previous month
- f. Financial summary of Recipient costs incurred by month to date, vouchers submitted, and Government payments made

16.2 Quarterly-In-Process Reviews. Scheduled as needed, generally not more frequently than quarterly, at the Recipient's facilities. Duration: 8 hrs max. Face to face review of previous quarter's activities. Informative in nature to keep BARDA apprised of project progress and to discuss issues that may require joint resolution, such as milestone changes, political impacts on objectives, schedule, funding.

16.3 Annual Financial Status Report. (37.880)

16.4 Final Report. Final Report shall not be marked proprietary, and shall have Distribution Statement C. Final report summarizing stated objectives and the progress that was achieved in meeting those objectives; summary of risks incurred, impacts and mitigation; quantitative discussion of vial production throughput improvements achieved; financial summary of project; schedule summary for project, comparing original schedule to final schedule; recommendations for path forward as applicable.

17. Modification of the Agreement

17.1 Limitation. In no event shall any understanding or agreement, modification, change order, or other matter in deviation from the terms of this agreement between the Recipient and a person other than the Agreement Officer be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the Agreement Officer. The only method by which this Agreement can be modified is by a formal, written modification signed by the Agreements Officer. No other communications, whether oral or in writing, shall modify this Agreement.

17.2 Recommendation. Modifications to this Agreement may be proposed by either Party. Recipient recommendations for any modifications to this Agreement, including justifications to support any changes to the proposal (inclusive of proposal revisions, proposal appendices, and the collaboration plan), as incorporated by reference, shall be submitted in writing to the Government Program Manager with a copy to the Agreements Officer. The Recipient shall detail the technical, chronological, and financial impact of the proposed modification to the program. Changes are effective only after this Agreement has been modified. The AO is responsible for the review and verification of any recommendations.

17.3 Unilateral or Minor. The AO may unilaterally issue administrative Agreement modifications (e.g., changes in the paying office or appropriation data, or changes to Government personnel identified in this Agreement, etc.). All other modifications shall be the result of bilateral agreement of the Parties. The Government may make minor or administrative Agreement modifications unilaterally.

18. Miscellaneous

18.1 Security. The Recipient shall not develop and/or handle classified information in the performance of this Agreement. No DD254 is currently required for this Agreement.

18.2 Entire Agreement. This Agreement, inclusive of the proposal, proposal revision, proposal appendices, and collaboration plan(s), constitutes the entire Agreement between the Parties concerning the subject matter hereof and supersedes any prior understandings or written or oral Agreement relative to said matter. In the event of a conflict between the terms of this Agreement, the terms of this Agreement shall govern.

18.3 Waiver of Rights. Any waiver of any requirement contained in this Agreement shall be by mutual agreement of the Parties hereto. Any waiver shall be reduced to a signed writing and a copy of the waiver shall be provided to each Party. Failure to insist upon strict performance of any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law, shall not be deemed a waiver of any rights of any Party hereto.

18.4 Liability. No Party to this Agreement shall be liable to the other Party for any property consumed, damaged, or destroyed in the performance of this Agreement, unless it is due to the negligence or willful misconduct of the Party or an employee or agent of the Party. In no event shall either Party be liable for special, incidental, or consequential damages arising from or connected with this Agreement.

18.5 Non-Assignment. This Agreement may not be assigned by any Party except by operation of law resulting from the merger of a Party into or with another corporate entity.

18.6 Severability. If any clause, provision or section of this Agreement shall be held illegal or invalid by any court, the invalidity of such clause, provision, or section shall not affect any of the remaining clauses, provisions, or sections herein, and this Agreement shall be construed and enforced as if such illegal or invalid clause, provision, or section had not been contained herein.

18.7 Force Majeure. Neither Party shall be in breach of this Agreement for any failure of performance caused by any event beyond its reasonable control and not caused by the fault or negligence of that Party. If such a force majeure event occurs, the Party unable to perform shall promptly notify the other Party and shall in good faith maintain such partial performance as is reasonably possible and shall resume full performance as soon as is reasonably possible.

18.8 Foreign Access to Technology & Domestic Manufacturing.

18.8.1 Activities Abroad. The Recipient shall assure that project activities carried on outside the United States are coordinated as necessary with appropriate Government authorities and that appropriate licenses, permits, or approvals are obtained prior to undertaking proposed activities. The awarding agency does not assume responsibility for Recipient compliance with the laws and regulations of the country in which the activities are to be conducted.

18.8.2 Export. The Parties understand that information and materials provided pursuant to or resulting from this Agreement may be export controlled, sensitive, for official use only, or otherwise protected by law, executive order, or regulation. The Recipient is responsible for compliance with all applicable laws and regulations. Nothing in this Agreement shall be construed to permit any disclosure in violation of those restrictions.

18.8.3. Exclusive right to use or sell the technology in the United States must, unless the Government grants a waiver, require that Products embodying the technology or produced through the use of the technology will be manufactured substantially in the United States (37.875).

The Parties realize and understand that the resultant Products of this TIA include components sourced from outside the U.S. because some components are not produced domestically or in sufficient quantities in the U.S. at this time.

18.9 Publicity. During the term of this Agreement, each Party will obtain the consent of the other Parties and the Government Program Manager before making any press releases or public statement pertaining to the Program or to this Agreement. This consent will not be unreasonably withheld. In addition, each Party will provide the other Parties (60) days in which to review and comment on proposed scholarly publications or presentations. The publishing Party shall take into account any comments received, and shall remove any other Party's Confidential Information that appears in the publication.

IN WITNESS WHEREOF, each Party has executed this Agreement by signature of its authorized representative.

SIGNATURES:

Recipient _____
 Signature **(b) (6)**

Printed Name
 CEO

Title 11 JUL 2020

Date

Government **(b) (6)**

Signature
(b) (6)

Printed Name
 Agreements Officer

Title

Date

Section J - List of Documents, Exhibits and Other Attachments

Exhibit/Attachment Table of Contents

DOCUMENT TYPE	DESCRIPTION	PAGES	DATE
Exhibit _	Smiths Medical and Marathon Amendment		10-JUL-2020
Attachment A	Smiths Medical Hypodermic Additional Capacity Proposal		30-JUN-2020
Attachment B	Collaboration Plan Statement of Objectives (SOO)		28-MAY-2020
Attachment C	Ganett Chart Master Schedule Phase 1 and 2		30-JUN-2020
Attachment D	BARDA SECURITY REQUIREMENT SOP		02-JUL-2020
Attachment E	Financial Worksheet Phase 1 and 2		30-JUN-2020
Attachment F	Direct Labor Cost Table Phase 1 and 2		30-JUN-2020
Attachment H	BARDA Program Management Org Chart		30-JUN-2020
Attachment I	BARDA CV Resumes Combined		30-JUN-2020

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE S	PAGE OF PAGES 1 4
2. AMENDMENT/MODIFICATION NO. P00002	3. EFFECTIVE DATE 03-Jun-2021	4. REQUISITION/PURCHASE REQ. NO. 0011506627-0001		5. PROJECT NO.(If applicable)
6. ISSUED BY USA CONTRACTING CMD-APG. - W911SR EDGEWOOD CONTRACTING DIVISION 8456 BRIGADE STREET BLDG E4215 ABERDEEN PROVING GROUND MD 21010-5401	CODE W911SR	7. ADMINISTERED BY (If other than item 6) DCMA TWIN CITIES - S2401A 5600 WEST AMERICAN BOULEVARD, SUITE 600 BLOOMINGTON MN 55111-4080		CODE S2401A
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) SMITHS MEDICAL ASD, INC. 6000 NATHAN LN N PLYMOUTH MN 55442-1690			9A. AMENDMENT OF SOLICITATION NO.	
			9B. DATED (SEE ITEM 11)	
			X 10A. MOD. OF CONTRACT/ORDER NO. W911SR2030005	
			X 10B. DATED (SEE ITEM 13) 11-Jul-2020	
CODE 52087	FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS				
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended.				
<p>Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods:</p> <p>(a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.</p>				
12. ACCOUNTING AND APPROPRIATION DATA (If required)				
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.				
A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.				
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).				
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:				
X D. OTHER (Specify type of modification and authority) Technology Investment Agreement (TIA)				
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input checked="" type="checkbox"/> is required to sign this document and return <u>1</u> copies to the issuing office.				
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Modification Control Number: (b) (6) See continuation page.				
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.				
15A. NAME AND TITLE OF SIGNER (Type or print)			16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
			TEL: (b) (6) EMAIL: (b) (6)	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. U BY (b) (6)		16C. DATE SIGNED
(Signature of person authorized to sign)		(Signature of Contracting Officer)		03-Jun-2021

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

MODIFICATION P00002

The purpose of this modification is to incorporate changes to W911SR-20-3-0005 Technology Investment Agreement (TIA) as follows:

1. Phase I: to remove from scope procurement of additional tooling at Smiths supplier to increase Syringe component capacity.
2. Phase II: to add scope for inclusion of a (b) (4) Syringe from (b) (4) in Combination devices in lieu of the original additional tooling at Smiths supplier to increase Syringe component capacity in Phase I scope.
3. Smiths Medical to provide (b) (4) needles and syringe combination innovative devices on the additional line in Phase II.
4. Build new (b) (4) mold tooling for Barrel, Plunger, and Tip (Gasket) in place (b) (4)
5. Build new (b) (4) assembly equipment in place at (b) (4)
6. Validate these new molds and equipment at the supplier and at Smiths Medical in Keene, NH.
7. The tooling and equipment will support a dedicated annual capacity of a total (b) (4) of combined 1cc and 3cc needle and syringe units with (b) (4).
8. Section J - List of Documents, Exhibits and Other Attachments Incorporate:
 - a. Modification Proposal W911SR2030005 Amendment 0004 dated 03May21 Final.
 - b. Attachment B- Collaboration Plan SOO v2 2021 04 15.
 - c. Attachment E-BARDA Revised Financial Worksheet Phase 1 and 2 03 May21.
 - d. Attachment E – BARDA Revised Financial Worksheet Phase 1 and 2 Amendment 0004-REDLINES.
 - e. Attachment F – Direct Labor Cost Table.
9. The parties hereto specifically agree that the work performed under this TIA is at no additional cost to the Government.
10. All other terms and conditions remain unchanged, except as noted herein.

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The Table of Contents has changed from:

Exhibit/Attachment Table of Contents

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Exhibit _	Smiths Medical and Marathon Amendment		10-JUL-2020
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Attachment F	Direct Labor Cost Table Phase 1 and 2		30-JUN-2020
Attachment H	BARDA Program Management Org Chart		30-JUN-2020
Attachment I	BARDA CV Resumes Combined		30-JUN-2020

to:

Exhibit/Attachment Table of Contents

DOCUMENT TYPE	DESCRIPTION	PAGES	DATE
Attachment	MODIFICATION PROPOSAL TIA AMENDMENT 0004	21	03-MAY-2021
Attachment B	UPDATED COLLABORATION PLAN SOO v2 2021 04 15	3	15-APR-2021
Attachment E	BARDA REVISED FINANCIAL WORKSHEET PHASE 1 AND 2	2	03-MAY-2021
Attachment E	EXCEL FINANCIAL PHASE 1 AND 2 AMENDMENT 0004 REDLINES		
Attachment F	DIRECT LABOR COST TABLE	2	

(End of Summary of Changes)

PROPOSAL MODIFICATION TIA W911SR2030005 – AMENDMENT 0004

Attention: DEPARTMENT OF THE ARMY
U.S. Army Contracting Command
8456 Brigade Street, E4215
Aberdeen Proving Ground, MD 21010-5401

Contracting Agency: Department of the Army

Contracting Office: Army Contracting Command, Aberdeen
Contracting Command (ACC-APG) Natick
and Edgewood Contracting Divisions (NCD
and ECD)

Program Office: Biomedical Advanced Research and
Development Authority (BARDA)

BAA Number: MSC-BAA-17-01-W911QY-17-S-0001
Amendment 0004

Topic Area, as Referenced from the BAA: Section VII.C.2 MEDICAL CHEMICAL
AND BIOLOGICAL
COUNTERMEASURES

Organization Submitting Proposal: Smiths Medical ASD, Inc.
6000 Nathan Lane North
Minneapolis, MN, 55442, USA

Proposal Title: BARDA/SMITH Medical - Hypodermic
Additional Capacity Proposal
Modification for (b) (4) Needle & Syringe
Combinations

Interested Points of Contact: Business: Technical:

(b) (6)	

Date Submitted: May 03, 2021
Updated: May 03, 2021 to reflect a change
to Phase I and Phase II for (b) (4) Needle &
Syringe Combination

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	• Direct Labor	
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	• Equipment Purchases	
	• Materials	
	• Source, Nature, and amount of proposed cost-sharing	
	• Any Forward Pricing Rate Agreement (FPRA) – Not applicable	
	• Proposers with a DCAA- approved cost accounting system	
	• Financial Information – See update and Attachment E	
V.	Additional Provisions.....	20

- VI. ATTACHMENT Updates..... attached
 - A. ATTACHMENT B: Collaboration Plan SOOattached
 - B. ATTACHMENT E: BARDA Financial Worksheet attached
 - C. ATTACHMENT F: Direct Labor Cost Table..... attached

II. EXECUTIVE SUMMARY

A. Executive Summary and Proposal for Modification to TIA # W911SR2030005

Smiths Medical, with global headquarters based in Plymouth, Minnesota, United States of America (USA), provides high-quality, cost-effective medical devices and consumables that are vital to patient care in the USA and globally. The company's mission is to help save and improve the lives of millions of patients, here in the USA and globally. Smiths Medical has five production sites, one service center, and one distribution center in the USA. Its location in Keene, New Hampshire, founded in 1971, assembles and packages needles and syringes among other vascular access products for the USA and global markets with 351 employees.

Due to shifting COVID-19 response requirements for lower dosage sizes and customer demand (b) (4) Smiths Medical proposes to assist BARDA in achieving its stated objective of increasing production capacity and delivering safety needles in combination with (b) (4)

This proposal focuses on modifying TIA #W911SR2030005 for Phase I and Phase II ("the additional Needle-Pro EDGE line), in order to produce (b) (4) needle & syringes that will assist in maximizing the number of doses from the Multi-dose COVID-19 vaccine vials.

The modification would allow Smiths Medical to produce (b) (4) needles and syringes for use in the delivery of COVID-19 vaccines, as well as supplies for any future pandemics in a cost efficient and highly effective manner. This Phase II (b) (4) modification replaces originally planned Phase I that (b) (4). This change will be at no additional Government cost share. The total cost has now been reduced to \$36,689,886 from previous \$37,205,802. The Government cost share has now been reduced from the previous \$20,663,774 and 55.5% to \$20,147,858 and 55.1%

Knowing the importance of hypodermic needles and syringes to COVID-19 response in the USA, the proposed modification continues to take the highest priority for Smiths Medical's leadership team. To increase our transparency (both internally and externally) and deliver the key milestones with full accountability.

The following table provides cost projections and timelines for the two overlapping phases.



III. VOLUME I - TECHNICAL PROPOSAL

A. Cover Sheet

1. TIA Number: W911SR2030005
Amendment 0004

2. Topic Area, as Referenced from the BAA: Section VII.C.2 MEDICAL CHEMICAL
AND BIOLOGICAL
COUNTERMEASURES

3. Organization Submitting Proposal: Smiths Medical ASD, Inc.
6000 Nathan Lane North
Minneapolis, MN 55442, USA

4. Proposal Title: BARDA/SMITH Medical - Hypodermic
Additional Capacity Proposal
Modification for (b) (4)
Needle & Syringe Combinations

5. Interested Points of Contact:

Business: (b) (6) [Redacted] [Redacted] [Redacted] [Redacted] [Redacted] [Redacted]	Technical: [Redacted] [Redacted] [Redacted] [Redacted] [Redacted] [Redacted]
--	--

6. Date Submitted: May 03, 2021
Updated: May 03, 2021 to reflect a change to
Phase I and Phase II for (b) (4) Needle & Syringe
Combination

B. Content

- 1. Innovative claims for the proposed effort. This section is the centerpiece of the proposal and should succinctly describe the uniqueness and benefits of the proposed effort and how it fulfills the objectives of the BAA.**

Smiths Medical's modification to the TIA # W911SR2030005 is to provide (b) (4) needles and syringe combination innovative devices on the additional line in Phase II which are well suited to help BARDA achieve the specific BAA objectives identified in the Request for Final Proposal sent to SmithsMedical by BARDA. Within the current investment from BARDA within the TIA, Smiths Medical proposes to (a) leverage product innovations, to (b) support (b) (4) requirements of the Multi-dose COVID vaccine.

With the revised contemplated investment from BARDA, Smiths Medical proposes to leverage (b) (4) innovations to achieve the objectives of this BARDA initiative, potentially in a manner that helps to reduce overall governmental costs.

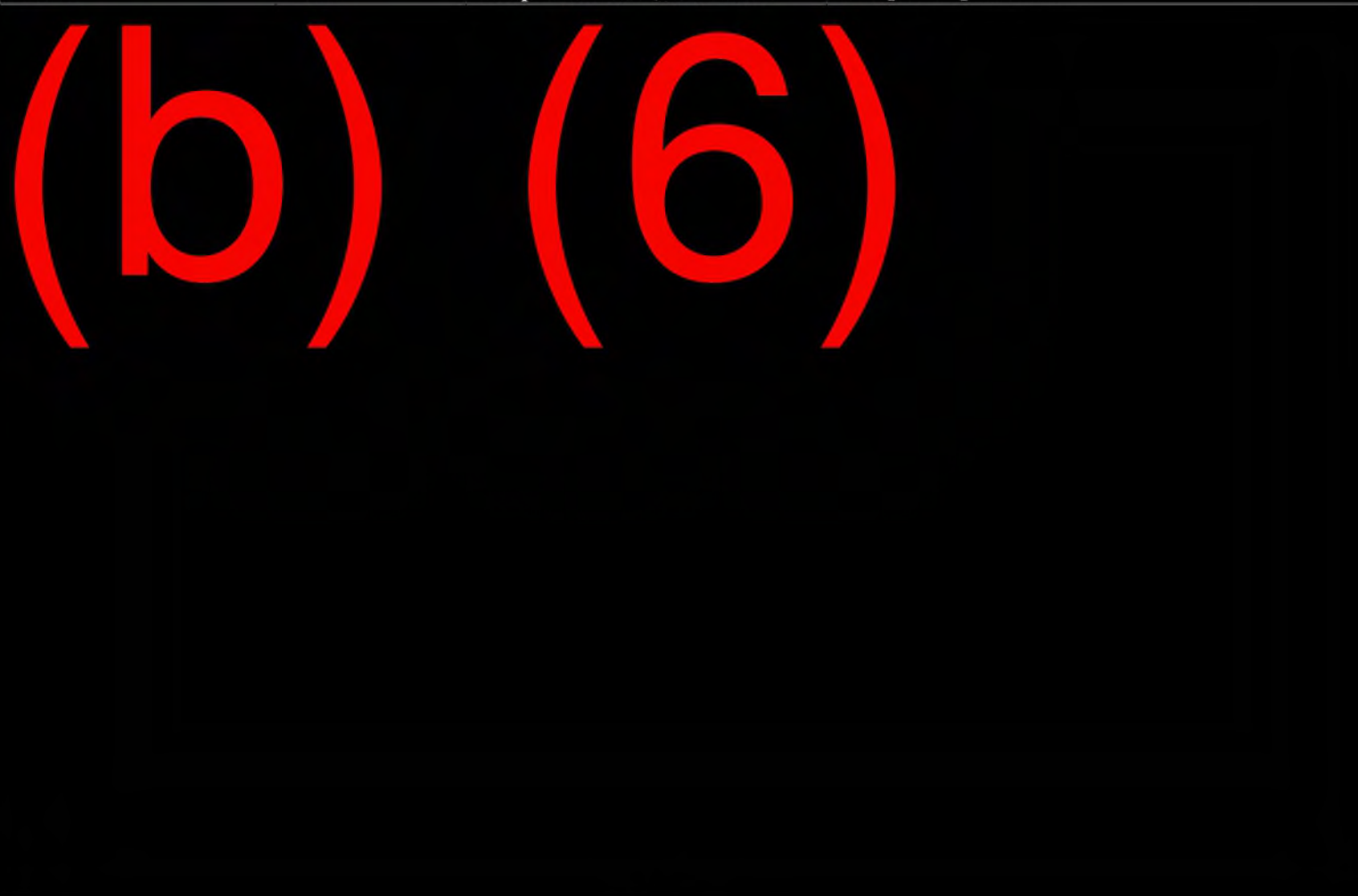
- 2. Technical rationale, technical approach, and plan for accomplishment of goals and objectives in support of innovative claims and proposed deliverables. Include in this section all proprietary claims to the results, prototypes, intellectual property, or systems supporting and/or necessary for the effort in question. If there are no proprietary claims, this should be stated.**

Smiths Medical produces hypodermic needle syringe combination devices in the Keene, New Hampshire facility. This facility has been in production since 1971 and has a proven track record of delivery and quality. The site has a world class staff with on-site automation, engineering, sourcing, planning, and Lean / Continuous Improvement (CI) resources.

When producing hypodermic needle syringe combinations, the site utilizes automated assembly equipment to accomplish this task efficiently and with high quality standards. The plan to achieve our delivery goals is focused around optimizing and expanding our current capacity as stated in the current TIA, but, with (b) (4) needle and syringe combinations in Phase II

3. A clearly defined organization chart for the program team which includes, as applicable: (1) the programmatic relationship of team member; (2) the unique capabilities of team members; (3) the task of responsibilities of team members; (3) the teaming strategy among the team members; and (5) the key personnel to be involved in the effort.

Below are the key personnel for the proposed project. (b) (6) will be the Senior Program Manager and will lead the internal governance and cadence of the program. As a teaming strategy, (b) (6) will utilize daily, weekly, and monthly check-ins with multiple workstreams. As project sponsor and a member of the Smiths Medical's Senior Leadership Team, (b) (6) will keep the Smiths Medical Senior Leadership Team, including our Chief Executive Officer (b) (6), informed of progress on a regular basis. This project has and will continue to have the full support of and oversight from the Smiths Medical Senior Leadership Team.

Name	Title	Senior Management Program Relationship, Responsibilities, and Tasks	Unique Capabilities
			

4. Discussion concerning any potential likelihood to leverage the effort for use among other Government organizations of interest if/as may be appropriate, along with any details concerning current use by other non-federal parties.

Currently, the U.S. demand is satisfied outside of the current COVID-19 situation and does not require Smiths Medical to add additional production capacity. Due to cost, customers outside the United States (OUS) predominantly use non-safety devices, so it is unlikely additional capacity would be used OUS. However, the (b) (4) needle and syringe combinations and related capacity expansion would be available for Strategic National Stockpile restocking and for future pandemic assistance within the United States and provide (b) (4) Needle & Syringe option for COVID-19 and future pandemics.

5. Statement of Work (SOW) :

This proposal Amendment is to reflect a change to Phase I and Phase II for inclusion of a (b) (4) in Combination devices.

Changes to Phase I are to remove from scope (b) (4)

Changes to Phase II are to add scope for inclusion of a (b) (4) Combination devices in lieu of the original (b) (4).

Refer to previous TIA and supporting documentation for other remaining unchanged workstreams within Phase I and Phase II.

The objective of the proposed project.

Consistent with the objectives articulated by BARDA in its Request for Final Proposal to Smiths Medical, our objectives for this proposal modification are to procure from our third party supplier Assembly Equipment and Injection Molding Tooling to secure a dedicated supply of an (b) (4) Syringes combined in both (b) (4)

A detailed description of the approach to be taken to accomplish the stated objective.

Due to shifting COVID-19 response requirements for lower dosage sizes and customer demand (b) (4) Smiths Medical proposes to assist BARDA in achieving its stated objective of increasing production capacity and delivering safety needles (b) (4)

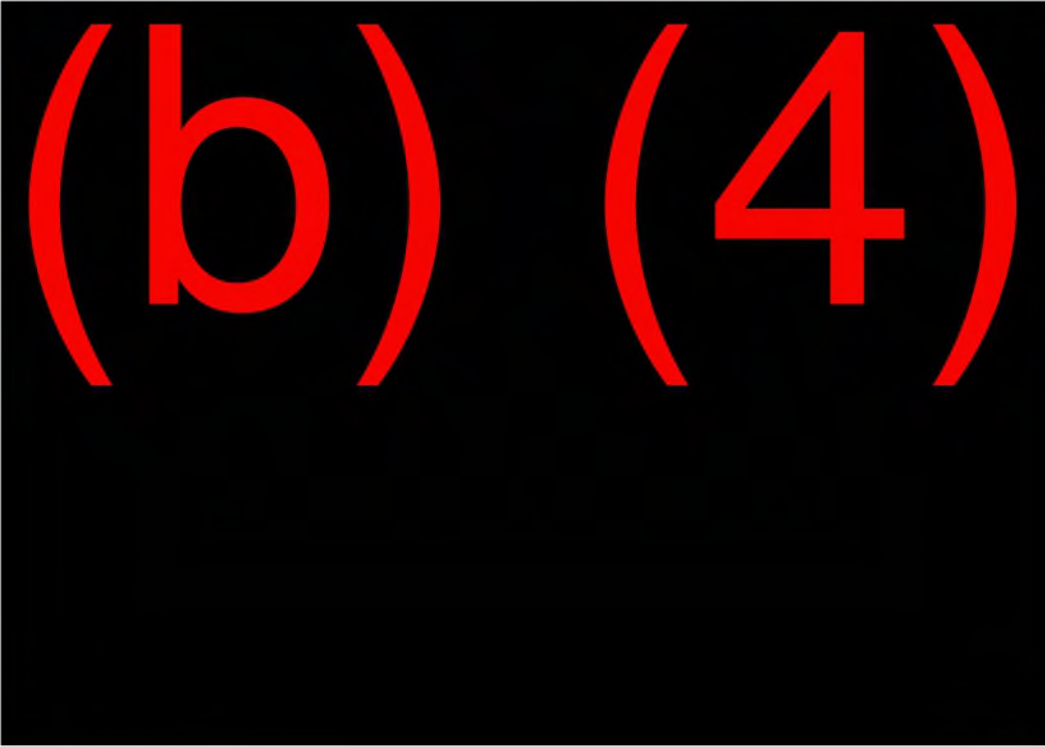
The approach Smiths Medical will take is to leverage an existing long-standing relationship with a third party supplier, (b) (4)

This proposal will ensure a secure dedicated Smiths Medical supply (b) (4) during Phase II execution as outlined below.



Smiths Medical has dedicated resources to project teams and begun initial preparations. As indicated above, a management structure has been created to ensure project teams have the necessary resources, the authority to make decisions, and a path for escalations and resolutions. Operating mechanisms (patterned project meetings, steering committee meetings, and the like) have been established to ensure progress and quick resolution to issues that may impede progress.

The measurable milestones involved & associated completion criteria for each involved.



Progress Reports

Task Name	
Monthly Review	1 months
Quarterly Review	3 months
Semi Annual Review	6 months
Quarterly Review	9 months

All deliverables (reporting, data, reports, etc.) to be provided to the Government in support of the proposed tasks/activities.

Quarterly Progress Reports. Submitted quarterly no later than the 10th calendar day of the quarter. Contractor format acceptable. Electronic submission acceptable in MS Office or PDF format. Financial information shall be MS Excel format. Quarterly reports shall NOT be marked proprietary, and shall have Distribution Statement C (US Government and their contractors). Each quarterly report shall, at a minimum, contain the following:

- a. Summary of quarterly progress for each of the recipient's facilities/capabilities associated with this effort.
- b. Summary of progress towards established milestones for each facility/capability.
- c. Identification of any milestone that is slipping or missed, and discussion of path forward to bring milestone back to schedule, and impact on other milestones.
- d. Summary of risks, discussion of potential impacts and efforts to mitigate.
- e. Summary of overall schedule and changes from previous quarter.
- f. Financial summary of recipient costs incurred by quarter to date, invoices submitted, and Government payments made.

Semi-Annual In-Process Reviews. Scheduled as needed, generally not more frequently than semi-annually, at the recipient's facilities. Duration: 8 hrs. max. Face to face review of previous two quarters' activities. Informative in nature to keep BARDA apprised of project progress and to discuss issues that may require joint resolution, such as milestone changes, political impacts on objectives, schedule, funding.

Annual Financial Status Report. See ALIN 4000.

Description of the facilities that would be used for the proposed effort.

Established in 1971, the Smiths Medical production facility in Keene, NH, USA, provides assembly and packaging for safety hypodermics, intravenous blood collection, arterial blood sampling, tracheostomy and pain management kits. It features a range of full and semi-automatic assembly and packaging equipment sets, as well as manual assembly and kitting. The site is (b) (4) square feet, including (b) (4) square feet of Cleanroom (Class 8/9) space. The facility is ISO Certified 13485 in Keene, NH.

ii. The Keene, NH, facility product range includes:

(b) (4)
[Redacted]
[Redacted]
[Redacted]

(b) (4)

iii. The Keene, NH, facility employs:

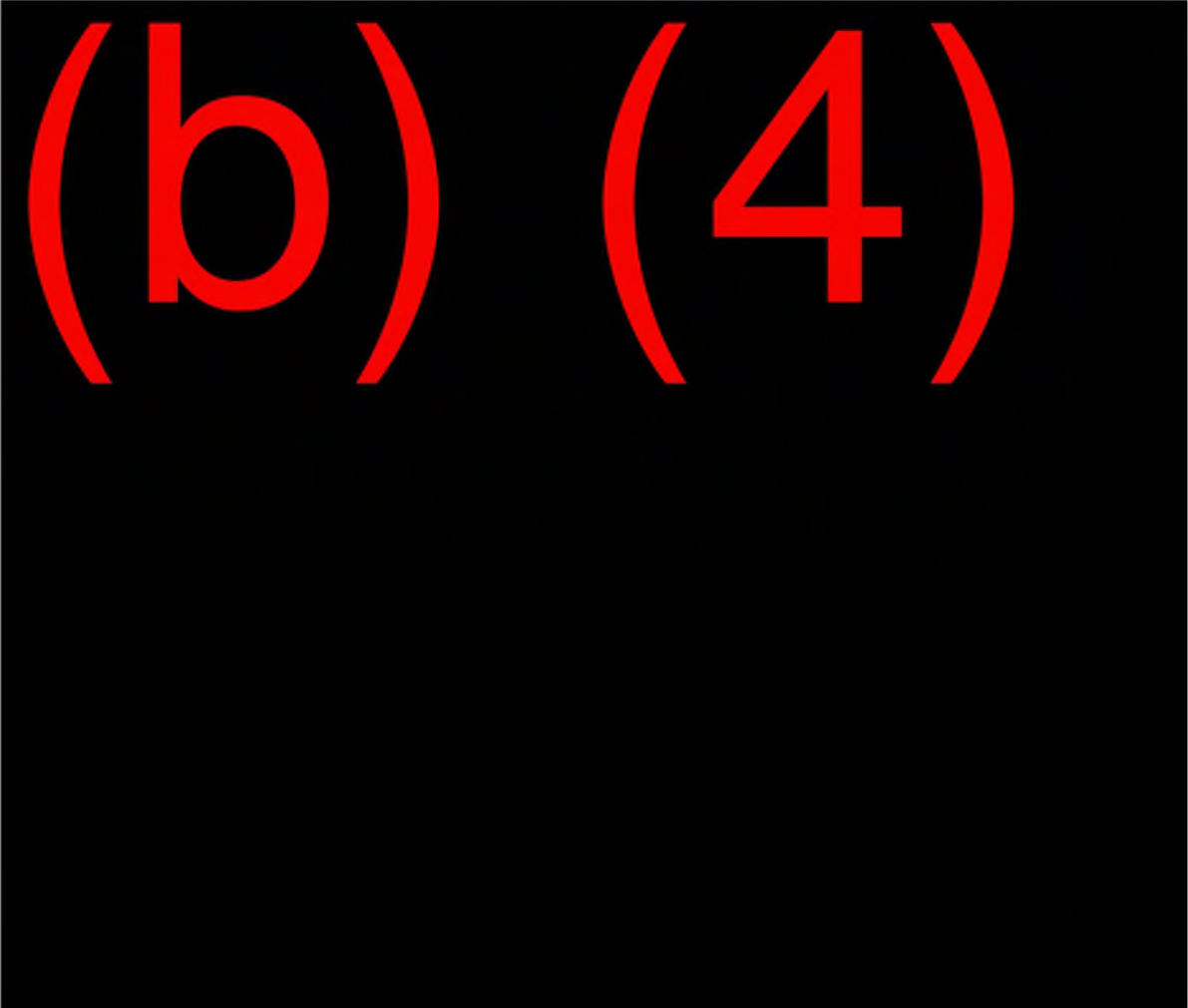
- a. Indirect Headcount: (b) (4) Total full-time employees (FTEs)
- b. Direct Headcount: (b) (4) Total FTEs
- c. Temp Headcount: (b) (4) FTEs
- d. Total Headcount: 351 FTEs

Capital and Commercial equipment to be purchased to achieve the proposed objective.

To achieve our first delivery of (b) (4), Smiths Medical will procure mold tooling and assembly equipment that will be placed at (b) (4). The tooling and equipment will support a dedicated annual capacity of (b) (4).

(b) (4)

Updates to Capital Plans for Phase I and Phase II as a result of this proposal are detailed in the tabled below.



Estimated direct labor hours (including labor categories) to be performed to achieve the proposed objective.

Total direct labor cost for the project is (b) (4). In order to simplify this proposal Smiths Medical has taken an average direct labor rate (b) (4) which is a volume weighted average direct labor rate for the resources required. Smiths Medical has laid out staffing requirements by function and by phase in the below table, which may also be found at ATTACHMENT F: Direct Labor Cost Table.

BARDA may also find below a functional abbreviation summary to decode the functional resources required from the summary.



Functional Abbreviations		
Ops	Site QE	Site Quality Engineering
	Site ME	Site Manufacturing Engineering
	AME	Operations: Advanced Manufacturing Engineering
	GLS	Operations: Global Sourcing
	LBL	Global Labeling
	MFE	Manufacturing Engineering
	SCN	Supply Chain Planning
	SQE	Supplier Quality Engineering
	MICROBIO	Microbiology
R&D	FUNCT ME	R&D Functional Engineering Mechanical Engineering
	PENG	Packaging Engineering
	PLE	Product Line Engineering
	TOX	Biocompatibility/Toxicology
GQR	QOM	Quality Operations - Microbiology
	DAS	Design Assurance
	Tech Comm	Technical Communications
	RAF	Regulatory Affairs
Misc.	FIN	Finance
	PM	Project/ Program Manager
	GPM	Global Product Management

IV. VOLUME II – Financial Aspects

A. Cover Sheet

1. TIA Number: W911SR2030005
2. Topic Area, as Referenced from the BAA: Section VII.C.2 MEDICAL CHEMICAL AND BIOLOGICAL COUNTERMEASURES
3. Organization Submitting Proposal: Smiths Medical ASD, Inc.
6000 Nathan Lane North
Minneapolis, MN 55442, USA
4. Proposal Title: BARDA/SMITH Medical – Hypodermic Additional Capacity Proposal
Modification for (b) (4) Needle & Syringe Combinations
5. Interested Points of Contact:

Business:	Technical:
(b) (6)	
6. Date Submitted: May 03, 2020
Updated: May 03, 2020 to reflect a change to Phase I and Phase II for (b) (4) & Syringe Combination
7. CAGE Code: 52087
8. DUNS Number: 056329097
9. Name, address, and phone number of administration (DCMA) office: N/A
10. Name, address, and phone number of audit (DCAA) office: N/A
11. Is this proposal consistent with your established estimating and accounting practices & procedures? If no, explain: Yes

B. Content

Financial Summary This financial volume provides data in sufficient detail to substantiate the reasonableness of the funding. All calculations and formulas are included with this financial information. The breakdowns herein include total requested funding, inclusive of all major cost items.

1. Direct Labor – including individual labor categories with associated labor hours and direct labor rates.

The total direct labor cost for the project is (b) (4). To simplify this proposal, we have taken an average direct labor rate of (b) (4) which is a volume weighted average direct labor rate for the resources required. We have laid out staffing requirements by function and phase in the below table, which may also be found at ATTACHMENT F: Direct Labor Cost Table. You can also find a functional abbreviation summary to decode the functional resources required from the summary.



2. Indirect Costs – Including Fringe Benefits, Overhead, General and Administrative (G&A) Expense, Cost of Money, Fee, etc. (must show base amount and rate).

The total indirect cost for all phases of this project is (b) (4). This is calculated by utilizing Smith Medical's corporate indirect burden rate of (b) (4) on top of our (b) (4) labor rate from section 2. A table of the breakdown of the burden rate of (b) (4) is included below.

Estimates for ODCs are built based on reviewing similar past projects, preliminary quotes and estimation from subject matter experts.

(b) (4)

6. **Equipment Purchases – Itemized list with associated costs, including quantities, unit prices, proposed vendors (if known), and the basis of estimate *e.g.*, quotes, prior purchases, catalog price lists, etc.); any item that exceeds \$10,000 must be supported with back-up documentation such as a copy of catalog price lists or quotes prior to purchase.**

Equipment required to execute Phases I - II includes assembly automation equipment and injection molding molds. The total estimated equipment cost for all two phases is

(b) (4)

To estimate equipment cost, Smiths Medical has reviewed: (a) quotes for similar equipment purchased in the past; and (b) preliminary quotes received from vendors for a portion of the equipment required for this project.

Smiths Medical routinely buys this type of equipment and has partnerships with multiple automation and tooling suppliers. Quotes will be competitively analyzed before approved.

a. Equipment Cost Summary by Phase:

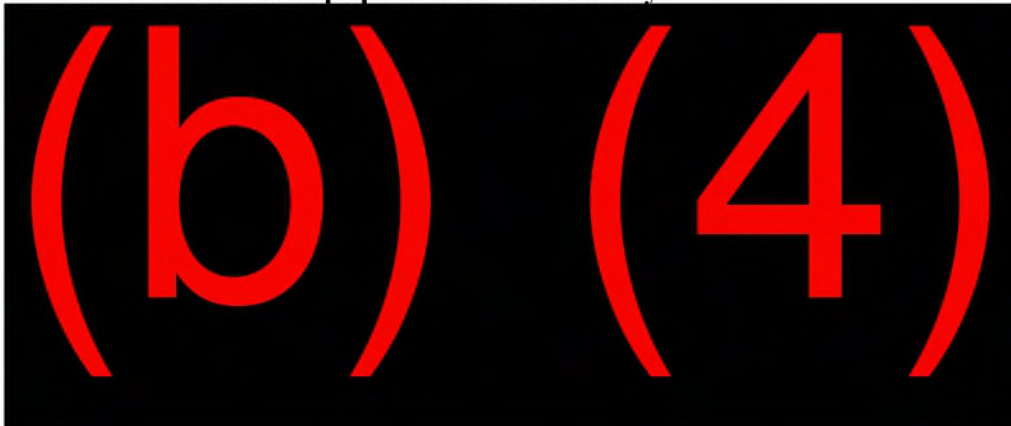
(b) (4)

b. Detailed Phase I Equipment Cost Summary:



removed from scope during in this Amendment in lieu of the new proposal.

c. Detailed Phase II Equipment Cost Summary:



- 7. Materials – Itemized list with associated costs, including quantities, unit prices, proposed vendors (if known), and the basis of estimate (e.g., quotes, prior purchases, catalog price lists, etc.); any item that exceeds \$10,000 must be supported with back-up documentation such as a copy of catalog price lists or quotes prior to purchase.**

Syringes and needles will be needed to qualify the new processes, SKUs, molds, tooling, and assembly lines. Please note these materials will not be used in production and are only utilized for ramp up. These materials will be sourced from Smiths Medical inventory, suppliers, and prototype partners. The total spend on materials is estimated at (b) (4)

(b) (4)

8. The source, nature, and amount of proposed cost-sharing.

The previous Government cost share was based on a total capacity investment of (b) (4) and assumes a 10-year useful life.

With this modification to provide (b) (4) needle and syringe combinations within Phase II, the total capacity investment has decreased to (b) (4)

With this in mind, below is the new cost-sharing on behalf of Smiths Medical in exchange for a total capacity investment of (b) (4) and assumes a 10-year useful life:

(b) (4)

9. Any Forward Pricing Rate Agreement (FPRA), other rate agreements, other documentation concerning approved rates, or any other such documentation that may assist in expediting negotiations (if available).

N/A.

10. Proposers with a DCAA-approved cost accounting system, must submit appropriate DCAA documentation that provides evidence of government approval of the cost accounting system.

N/A.

11. Requests for Pre-Award Cost authorizations IAW 32 CFR 37.830 require a written agreement between the potential awardee and the Agreements Office prior to expenditure commencement.

Smiths Medical understands and agrees to abide by this requirement.

V. ADDITIONAL PROVISIONS

- A. Confidentiality.** This document and ATTACHMENTS contain confidential and proprietary commercial and trade secret information that is protected from public disclosure under the Federal Food, Drug, and Cosmetic Act, the Freedom of Information Act, FDA's implementing regulations, and the Trade Secrets Act. If a request for disclosure is received, the Company requires that it be notified and provided an opportunity to address why the information or materials should not be released or, in the event that the applicable government agency determines that documents or materials containing such confidential or proprietary information should be released, the Company requests that it be permitted to perform appropriate redactions.
- B. Intellectual Property.** Pre-existing proprietary and confidential property, including patented, copyrighted and trademarked property, of Smiths Medical and its third-party suppliers is and shall remain the property of Smiths Medical and its third-party suppliers. Any and all materials, designs, or other intellectual property created, developed, or reduced to practice by Smiths Medical in connection with the work performed under an awarded contract, including designs, inventions, works of authorship, prototypes, and processes (the "Work Product") will remain the property of the Smiths Medical. The Government shall acquire no rights in the above-referenced property, including but not limited to any licenses to use, modify, or create derivative works. The Government shall not share such information with third parties without specific written permission of Smiths Medical or its relevant third-party supplier.
- C. Non-Binding Proposal.** Submission of this proposal by Smiths Medical does not in anyway constitute an offer to enter into a contract, or otherwise perform or render any services or products as part of a contract, obligating either Smiths Medical or the Government. The Government's acceptance of this proposal shall only constitute an invitation by the Government to enter into formal negotiations with Smiths Medical to seek to enter into a legally binding contract to perform the services and produce the products for purchase by the Government described in the proposal.
- D.** Except as specified in this modification, no other changes are made to the TIA W911SR2030005

B. Agreement

B.1. The Government intends to award up to one (1) Technology Investment Agreement (TIA) or Grants to Smiths Medical in response to this solicitation, which is issued under Broad Agency Announcement MSC-BAA-17-01-W911QY-17-S-0001 Amendment 0004, Section VII.C.2 MEDICAL CHEMICAL AND BIOLOGICAL COUNTERMEASURES.

B.2. If a TIA is awarded as a result of this solicitation, it will be executed under the authority 10 USC 2371 - Research Projects other than contracts and grants, which requires cost sharing between the Government and recipient. The expenditure-based TIA cost sharing ratio shall begin with a 50/50 Government/Awardee share ratio. The recipient's cost share comprised of allowable project investment costs including, but not limited to in-house labor and subcontracted costs, equipment utilization and capital equipment costs incurred by the recipient in achieving the objectives of this effort. See 32 CFR 37.215(b).

B.6. Agreement Line Items (ALIN)

ALIN 1000: Development/Expansion of manufacturing capacity for hypodermic safety needles and corresponding syringes in accordance with the Statement of Objectives outlined in Section C below.

ALIN 2000: Monthly progress reports. 2001, 2002, 2003 etc.

ALIN 3000: Quarterly In-Process Reviews (IPR) Hosted at the recipient's facilities. 3001, 3002, 3003 etc.

ALIN 4000: Annual Financial Status Report

ALIN 5000: Final Report that details the findings and issues of the completed project. C.

Statement of Objectives

C.1. Introduction.

C.2. General Objectives.

The recipient shall expand existing domestic Continental US (CONUS) based safety needle and syringe infrastructure and surge capacity to support response for medical countermeasures, emerging infectious diseases and other threats of known and unknown origin during a public health emergency. In the event that existing capacity is unavailable, the recipient shall identify, develop and qualify new US-based manufacturing and supply base for utilization with USG (BARDA and affiliate partners) MCMs. In the event of the declaration of a public health emergency, the recipient shall provide priority access to this new or existing MCM capacity for BARDA and other Federal agencies authorized by BARDA. Expansion of existing domestic capacity shall be through accelerated expansion of assembly lines, molding lines, packaging lines, tooling and any other related manufacturing capabilities in existing recipient facilities or using manufacturing capabilities at recipient's third party suppliers.

C.3. Specific Objectives.

C.3.1. The recipient shall increase the throughput of existing domestic manufacturing capabilities by a minimum of 50% to enable the USG to expedite MCM administration/delivery to meet US COVID-19 MCM demand. Expansion/development sites include, but are not limited to:

- Expansion safety needle and syringe manufacturing capacity in Keene, NH

- Expansion of (b) (4) e capacity at recipient's supplier, (b) (4), dedicated to recipient's supply only.

C.3.2. The minimum throughput target for Smiths Medical's needle and syringe manufacturing capabilities is defined as achieving an added capacity of not less than (b) (4) safety needle and syringe units.

C.3.3. Upon completion of the effort, the USG, through BARDA, shall receive priority access to facilitate third party purchase of safety needles and syringes produced through this investment effort for COVID-19 medical countermeasures.

C.4. Schedule Objectives.

The schedule for this effort shall be from date of award (anticipated June 2020) through August 30, 2021. Incremental capacity will become available quarterly beginning in 2021. However, more rapid acceleration is highly desired by the Government in order to meet critical COVID-19 response needs. As acceleration opportunities are identified, the recipient is encouraged to work with USG BARDA to make optional incremental funding to realize these opportunities. As incremental capabilities become available from different component facilities, they shall be placed online as quickly as possible and made available to USG BARDA to meet critical national COVID-19 demands.

C.5. Overall Management Objectives.

The recipient shall be responsible for overall management and oversight of the work necessary to achieve the objectives of this agreement. The recipient shall provide the overall management, integration, and coordination of all agreement activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all agreement activities.

The recipient shall establish project milestones for each facility/capability for which expansion and/or development is planned. Incremental progress against each milestone shall be provided to BARDA in accordance with established deliverables (see C.9 below). Any changes or deviations planned or incurred by the recipient in pursuing the objectives of this agreement shall be reported to BARDA. While primary responsibility for management and execution of the effort resides with the recipient, BARDA shall have input to the milestone review process and any changes to the objectives of the agreement. BARDA shall have the responsibility for communicating to the recipient any changes in USG MCM strategies that may impact this agreement.

C.6. Risk Management Objectives.

The recipient shall identify all anticipated project risks categorized as moderate or high and report them to BARDA in accordance with reporting requirements (see C.9 below). The recipient shall manage all project risks using its in-house risk management capabilities, and report to BARDA changes to all identified risks as

they occur/arise. BARDA shall be permitted to participate in the risk management and mitigation processes associated with this project.

C.7 Physical Property.

Title to all physical property developed under this Agreement shall vest with Smiths Medical.

C.8. Intellectual Property.

Intellectual Property rights for all technology developed under this agreement shall reside with Smiths Medical, with the exception of information contained in specified deliverables, which shall be subject to distribution within US Government agencies and their contractors (Distribution Statement C). See C.9 below.

C.9. Deliverables.

C.7.1. Monthly Progress Reports. See ALIN 2000. Submitted monthly no later than the 10th of the month. Contractor format acceptable. Electronic submission acceptable in MS Office or PDF format. Financial information shall be MS Excel format. Monthly reports shall NOT be marked proprietary, and shall have Distribution Statement C (US Government and their contractors). Each monthly report shall, at a minimum, contain the following:

- Summary of monthly progress for each of the recipient's facilities/capabilities associated with this effort.
- Summary of progress towards established milestones for each facility/capability.
- Identification of any milestone that is slipping or missed, and discussion of path forward to bring milestone back to schedule, and impact on other milestones.
- Summary of risks, discussion of potential impacts and efforts to mitigate.
- Summary of overall schedule and changes from previous month.
- Financial summary of recipient costs incurred by month to date, invoices submitted, and Government payments made.

C.7.2. Quarterly In Process Reviews. See ALIN 3000. Scheduled as needed, generally not more frequently than quarterly, at the recipient's facilities. Duration: 8 hrs max. Face to face review of previous quarter's activities. Informative in nature to keep BARDA apprised of project progress and to discuss issues that may require joint resolution, such as milestone changes, political impacts on objectives, schedule, funding.

C.7.3. Annual Financial Status Report. See ALIN 4000

C.7.4. Final Report. See ALIN 5000. Final Report shall NOT be marked proprietary, and shall have Distribution Statement C. Final report summarizing stated objectives and the progress that was achieved in meeting those objectives; summary of risks incurred, impacts and mitigation; quantitative discussion of needle and syringe production throughput improvements achieved; financial summary of project; schedule summary for project, comparing original schedule to final schedule; recommendations for path forward as applicable.

Year 1 (Jun '20 - May '21)

Year 2 (Jun '21 - May '22)

Year 3-10 (Jun '22 - May '29)

Amendment - 0004

(b)

(4)

(b) (4)

Labor Staffing Estimates by phase by workstream (100%=1 dedicated FTE)																													
														Ops				R&D				GQR				OTHER			
(b) (4)																													

Functional Abbreviations		
OPS	Site QE	Site Quality Engineering
	Site ME	Site Manufacturing Engineering
	AME	Operations: Advanced Manufacturing Engineering
	GLS	Operations: Global Sourcing
	LBL	Global Labeling
	MFE	Manufacturing Engineering
	SCN	Supply Chain Planning
	SQE	Supplier Quality Engineering
	MICROBIO	Microbiology
	R&D	FUNCT ME
PENG		Packaging Engineering
PLE		Product Line Engineering
TOX		Biocompatibility/Toxicology
QOR		Quality Operations - Microbiology
	DAS	Design Assurance
	Tech Comm	Technical Communications
	RAF	Regulatory Affairs
Misc.	FIN	Finance
	PM	Project/ Program Manager
	GPM	Global Product Management

FINAL PROPOSAL

Attention: DEPARTMENT OF THE ARMY
U.S. Army Contracting Command
8456 Brigade Street, E4215
Aberdeen Proving Ground, MD 21010-5401

Contracting Agency: Department of the Army

Contracting Office: Army Contracting Command, Aberdeen
Contracting Command (ACC-APG) Natick
and Edgewood Contracting Divisions (NCD
and ECD)

Program Office: Biomedical Advanced Research and
Development Authority (BARDA)

BAA Number: MSC-BAA-17-01-W911QY-17-S-0001
Amendment 0003

Topic Area, as Referenced from the BAA: Section VII.C.2 MEDICAL CHEMICAL
AND BIOLOGICAL
COUNTERMEASURES

Organization Submitting Proposal: Smiths Medical ASD, Inc.
6000 Nathan Lane North
Minneapolis, MN, 55442, USA

Proposal Title: BARDA/SMITH Medical - Hypodermic
Additional Capacity Proposal

Interested Points of Contact:	Business:	Technical:
	(b) (6)	(b) (6)
	(b) (6)	(b) (6)
	(b) (6)	(b) (6)
	Smiths Medical	6000 Nathan Lane N
	6000 Nathan Lane N.	Plymouth, MN 55442
	Plymouth, MN 55442	(b) (6)
	(b) (6)	(b) (6)
	(b) (6)	(b) (6)
	(b) (6)	(b) (6)

Date Submitted: June 02, 2020
Updated: June 30, 2020 to reflect Phase I
and Phase II Only

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- X. ATTACHMENTS attached
 - A. ATTACHMENT A: EDGE™ Product Summary attached
 - B. ATTACHMENT B: EDGE™ Safety Hypodermic Devices attached
 - C. ATTACHMENT C: Gantt Chart - Master Schedule attached
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 - E. ATTACHMENT E: BARDA Financial Worksheet attached
 - F. ATTACHMENT F: Direct Labor Cost Table attached
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 - H. ATTACHMENT H: Smiths Medical Project Management Org Chart.....attached
 - I. ATTACHMENT I: CV's for Projection Management Team.....attached

II. EXECUTIVE SUMMARY

A. Executive Summary and Proposal for Expanding Domestic Production of Needles & Syringes

Smiths Medical, with global headquarters based in Plymouth, Minnesota, United States of America (USA), provides high-quality, cost-effective medical devices and consumables that are vital to patient care in the USA and globally. The company's mission is to help save and improve the lives of millions of patients, here in the USA and globally. Smiths Medical has five production sites, one service center, and one distribution center in the USA. Its location in Keene, New Hampshire, founded in 1971, assembles and packages needles and syringes among other vascular access products for the USA and global markets with 351 employees.

This proposal focuses on the expansion of Smiths Medical's capacity and infrastructure in Keene, NH, to support the request from the Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary of Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS), for expanding domestic assembly of needles and syringes due to the onset of the COVID-19 pandemic. Smiths Medical's work on this contract would be in support of BARDA's existing contract with Marathon Medical Corporation (contract #HHSO1002018000131), an authorized distributor of Smiths Medical's hypodermic needles and syringes.

The capacity and infrastructure expansion contemplated for Keene, NH, under this new contract would allow Smiths Medical to produce additional needles and syringes for use in the delivery of COVID-19 vaccines, as well as supplies for any future pandemics in a cost efficient and highly effective manner. Smiths Medical's EDGE™ hypodermic needle and syringes provide distinct additional benefits compared to the alternatives in the market:

1. With an engineered safety mechanism, Smiths Medical hypodermics help to prevent needlestick injuries to hundreds of thousand care providers. Each of these injuries occurs at an estimated cost of \$3,042 per event for the front-line workers who are exposed every day.¹
2. With less residual volume of medication left in the delivery device ("deadspace")², Smiths Medical's Needle-Pro® EDGE™ hypodermic needle and syringes reduce medication waste and thus expenses allowing maximum utilization of the vaccines available.
3. Medication waste of drugs represents \$3 billion a year and affects cost of care.⁵
4. Quality and reliability: The Keene, NH site has the highest certifications (*e.g.*, ISO13485) and a world-class experienced team of engineers and experts onsite.

Knowing the importance of hypodermic needles and syringes to COVID-19 response in the USA, the proposed expansion of capacity and infrastructure would take the highest priority for Smiths Medical's leadership team. To increase our transparency (both internally and externally) and deliver the key milestones with full accountability, Smiths Medical proposes to undertake all work under the agreement in two overlapping phases for a total capacity of up to 125+ million incremental units over a period of 18 months from agreement execution, as summarized in the next subsection.

B. This proposal contemplates two (2) overlapping phases of capacity and infrastructure expansion at Smiths Medical's facility in Keene, NH:

- 1. Phase I: Line Optimization and Tooling.** This phase will qualify new packaging lines releasing capacity the Needle-Pro® and EDGE™ assembly lines in Keene, NH, USA. This phase also purchases additional molds for syringe and EDGE™ components. This phase includes production and delivery of (b) (4) incremental units.
- 2. Phase II: Duplicate Automated Line.** This phase will duplicate the EDGE™ assembly line in Keene, NH, USA. This phase includes production and delivery of 70 - 75 million incremental units.

With the implementation of the two overlapping phases, this proposed expansion of production capacity in Keene, NH, will achieve BARDA's three specific contract objectives of: (1) increasing throughput of existing domestic production capability by at least 50%, enabling the U.S. Federal Government (USG) to expedite Medical Countermeasure (MCM) administration and delivery to meet U.S. COVID-19 MCM demand; and (2) adding capacity of no less than 110 million safety needle and syringe units. Upon completion of the effort, (3) the USG, through BARDA, will also receive priority access to facilitate purchase of safety needles and syringes, through Smiths Medical's authorized distributor, Marathon Medical, produced through this investment effort for COVID-19 MCMs.

This approach enables the availability of Centers for Disease Control and Prevention (CDC)-recommended syringe sizes³. The implementation of all two phases is at a total cost of \$37,205,802, benefitting a U.S.-centric supply base for key spend areas, such as capital equipment. The Smiths Medical supply team has already identified and engaged potential key suppliers, such as those that may support the line duplication and device sterilization. In addition, Smiths Medical's regulatory team has started work to accelerate product validations and supplier qualifications.

Smiths Medical has proactively identified potential risks (*e.g.*, syringe sourcing) and is working to mitigate those risks. We believe the contemplated additional capacity will help Smiths Medical to support and deliver the COVID-19 response efforts for the USG in peak periods, as well as enable the replenishment of stock for the next 10+ years for any future needs, including pandemics. The Smiths Medical team has proposed a robust governance program for BARDA, including regular reviews and reports, as well as burden sharing arrangements to drive our ownership both now and well into the future.

The proposal details out our capabilities, execution plans, costs, and details on delivering the hypodermic needle and syringe capacity for U.S. domestic needs.

III. OVERVIEW OF PRODUCTS

A. Hypodermic Needle and Syringe Overview

Needles are the most widely used medical device with an estimated 16 billion injections administered each year, often used for drug delivery, vaccinations, and injections.² Exposure of blood borne pathogens, including Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human Immunodeficiency Virus (HIV), by needle stick injuries (NSI) is a risk to healthcare professionals (HCP). This exposure risk was a driving force for legislation in the United States mandating needle safety devices and the adoption of safety devices has dramatically reduced NSI since their introduction. Needle-Pro® EDGE™ Safety Devices are safety engineered to help prevent needle stick injuries (NSI) and provide less “deadspace” when compared to a conventional, non-safety needle¹; thereby reducing medication waste, which can be critically important during a pandemic.

Smiths Medical will provide combined needle and syringe units that are sterile and individually wrapped, U.S. Food & Drug Administration (FDA) 510(k) cleared, and incorporates a safety engineered feature. This device is intended for use to inject fluids into or withdraw fluids from the body. The safety engineered feature is an integral protection device that covers the needle after use to help prevent needle stick injuries. The Needle-Pro® EDGE™ product has very low “deadspace” and therefore may reduce medication waste when compared to most similar products².

1. Prevent Needlestick Injuries with an Engineered Safety Mechanism

- a. Each year, needlestick and sharps injuries affect more than half a million healthcare personnel and cost over \$1 billion in healthcare costs.⁴
- b. The estimated cost of a needlestick is \$3,042 per incident.⁴
- c. The Needle-Pro® EDGE™ hypodermic offers a single-handed safety-activation device that helps to prevent needlesticks.¹

2. Reduce Medication Expenses / Preserve Vaccines and Medications

- a. Deadspace is the total residual volume of medication in the cannula, hub, or luer of the needle following injection of a needle and syringe combination.
- b. Medication waste of certain wasted drugs can represent up to \$3 billion a year and affect the cost of healthcare.⁵
- c. The Needle-Pro® EDGE™ hypodermic needle offers the lowest deadspace available on the market, ensuring dosage accuracy and less wasted medication.⁸ The following chart provides a quick market comparison, and additional information ATTACHMENT D: Needle-Pro® EDGE™ Safety Device Deadspace.

(b) (4)

EDGE™ Safety Hypodermic Devices technology combines the benefits of an advanced safety hypodermic needle with the deadspace profile of a conventional needle.¹

3. Proposed Devices for Vaccine Administration



Clinicians determine which needle gage size (22G- 25G) and length are appropriate based upon recommended guidelines from the Centers for Disease Control and Prevention of the U.S. Health and Human Services Department.

Item #	Description
412315	Hypodermic Needle/Syringe Combo ⁶ , 1mL, 23G x 1.5”
412510	Hypodermic Needle/Syringe Combo ⁶ , 1mL, 25G x 1”
412558	Hypodermic Needle/Syringe Combo, 1mL, 25G x 5/8”
432510	Hypodermic Needle/Syringe Combo, 3mL, 25G x 1”
432315	Hypodermic Needle/Syringe Combo ⁶ , 3mL, 23G x 1.5”
4236	Hypodermic Needle/Syringe Combo, 3mL, 23G x 1”
4234	Hypodermic Needle/Syringe Combo, 3mL, 22G x 1.5”

IV. COST PROPOSAL OVERVIEW

A. Overview of Cost Proposal

Smiths Medical is a proven supplier and seeks to assist in providing the USG hypodermic devices necessary to expedite MCM administration / delivery to meet US COVID-19 MCM demand. As a leading producer of hypodermic safety devices, Smiths Medical has developed sufficient capacity to supply its commercial base of customers and also has a surge capacity of approximately 70 - 75 million (M) needle / syringe units annually. Pursuant to an existing agreement, contract #HHSO1002018000131, BARDA recently provided orders to Marathon Medical, Smiths Medical's authorized distributor, that will consume this additional surge capacity over the next year. Post-pandemic, and without significant increases in the commercial base business, our current capacity meets our normalized run-rate business.

Smiths Medical's Keene, NH, facility has the physical space to produce an additional 150 million units annually. The commercial business does not justify installing additional production capacity. The United States will benefit from a readiness posture for COVID-19 and to address potential future pandemics and outbreaks.

The cost and timeline proposed in this document reflects Smiths Medical's best current estimates. Consistent with Smiths Medical's regular procurement practices, these estimates are based on: (1) a detailed bottom-up timeline and cost estimate built for this project; (2) analyzing timelines and cost- for similar scope projects in the past.

All actual spend for this project outside of Smiths Medical (*e.g.*, equipment, materials, and other direct costs) will go through Smiths Medical sourcing/procurement process/governance. Smiths Medical on a yearly basis procures (b) (4) of spend through third party sources. All of this spend goes through a robust governance and source-to-pay process. Smiths Medical has a procurement organization with 30+ sourcing professionals who on a daily basis ensure all 3rd party spend has proper quality, delivery, and cost. (b) (6) of Global Sourcing, will be a key leader of this project and will oversee the success of all supplier interdependencies for this project. He is a part of the Smiths Medical Senior Leadership Team and will bring the support of senior leadership as needed.

Understanding the urgency of this proposal due to COVID-19, Smiths Medical has proposed an aggressive timeline to accomplish the two phases articulated in this proposal. Smiths Medical has identified risks associated with those timelines and has detailed them later in this document, along with proposed mitigation strategies.

1. Equipment and Labor. The largest cost contributors for this project are equipment and labor.

a. Equipment. Consistent with our standard operating procedures, Smiths Medical has estimated equipment costs by reviewing: **(i)** past quotes for similar equipment; and **(ii)** preliminary quotes for a portion of the required equipment received from vendors in connection with this proposal to BARDA from Smiths Medical.

Smiths Medical routinely buys this type of equipment and has partnerships with multiple automation and tooling suppliers. Quotes will be competitively analyzed before being approved.

All equipment spend will follow Smiths Medical's Capital Equipment Purchasing Process DOC # B10001875, details about which may be found in ATTACHMENT G.

b. Labor. The second largest cost contributor for this project is labor. To estimate labor cost, including the number of staffing hours, Smiths Medical reviewed similarly scoped projects and built a detailed staffing model, inventorying the many functions across Smiths Medical that will be involved in this project. The project will require time from 20 different Smiths Medical functions and individuals. Additional Details on these costs can be found in Section VII: Volume II.

Below is a recap of Smiths Medical's cost proposal for the two overlapping phases of capacity and infrastructure expansion for BARDA, used for the delivery of COVID-19 vaccines. Further cost detail is outlined below in Volume II and in ATTACHMENT E: BARDA Financial Worksheet v4.

B. Smiths Medical's proposal includes Two (2) Overlapping Phases of Capacity and Infrastructure Expansion, assuming a June 1, 2020 Start Date

Smiths Medical's proposal includes two overlapping phases adding up to 125+ million units of capacity for \$37,205,802 of investment. The two phases are summarized:

- 1. Phase I: Line Optimization and Tooling.** This phase will qualify new packaging lines to free up the Needle-Pro® and EDGE™ assembly lines in Keene, NH. This phase also purchases additional molds for syringe and EDGE™ components. The associated cost for packaging equipment and supplier mold tooling is (b) (4)
- 2. Phase II: Duplicate Automation Line.** This phase will duplicate the EDGE™ assembly line in Keene, NH, USA, doubling throughput. Line extension requested for BARDA's COVID-19 needle and syringe vaccine requirements, development of two additional 1ml SKUs⁶ and one additional 3ml SKU⁶. The associated cost for duplicating the automated assembly line and new product development of the three new SKUs is (b) (4)

The following table provides cost projections and timelines for the two overlapping phases.



C. Note About Pre-Proposal Cost

During the course of completing a more thorough financial review for this proposal and modifying the proposal to include only Phase 1 and Phase 2, Smiths Medical identified the total proposed project cost of up to \$37,205,802.

D. Cost Summary

With the implementation of the two phases at a total cost of \$37,205,802, the proposed expansion will increase Smiths Medical's domestic output over 100% to enable the USG to expedite MCM administration / delivery to meet U.S. COVID-19 MCM demand and add capacity of up to 125+ million safety needle and syringe units, meeting BARDA's specific program objective of not less than 110 million safety needle and syringe units.

Much of the cost for this project stems from capital and equipment purchases, which account for (b) (4) This equipment has a typical useful life 15 - 20 years and will ensure increased domestic capacity for hypodermic needles not only for the nation's current COVID-19 response but also possible future pandemics the country could face. Labor accounts for (b) (4) of the costs of this project and encompasses the many engineering and execution hours required to procure, install, and validate multiple highly complex syringe assembly lines and the development of a syringe design. Materials, other direct costs, and operational costs account for (b) (4) of the project, detailed cost information can be found in the Section V: Technical Response, Section VII: Volume II, and ATTACHMENT E: BARDA Financial Worksheet v4.

V. TECHNICAL PROPOSAL

A. Statement of Work Summary

As expounded in the full Statement of Work below in Volume I, Smiths Medical proposes a Statement of Work that focuses on: (1) the satisfaction of key objectives, (2) the employment of a phased approach, (3) the attainment of objectively measurable milestones, (4) the regular delivery of reports to BARDA, and (5) the use of its facilities in Keene, NH, for all project production.

1. **Objectives.** Smiths Medical proposes to adopt the specific project objectives identified by BARDA in its Request for Final Proposal sent to Smiths Medical. In brief, Smiths Medical seeks to support BARDA's effort to expand domestic needle and syringe infrastructure; increase throughput of existing domestic production capability by at least 50%; achieve a target of not less than 110 million new safety needle and syringe units; and provide the USG, through BARDA, priority access to facilitate third party purchase of safety needles and syringes produced through this investment effort for COVID-19 medical countermeasures through BARDA's existing contract with Marathon Medical.
2. **Approach.** To achieve those objectives, Smiths Medical proposes to simultaneously undertake two overlapping phases of activity, adding up to 125+ million units of capacity for \$37,205,802 of investment. The two phases are summarized:
 - a. **Phase I: Line Optimization and Tooling**
Smiths Medical will increase its capacity by an additional (b) (4) units ((b) (4) EDGE™ / (b) (4) Needle-Pro®) annually in its Keene, NH, facility in 7-9 months by transferring non-hypodermic syringe combination device production to another Smiths Medical site.
 - b. **Phase II: Duplicate Line and New Product Development**
Smiths Medical will increase its capacity an additional (b) (4) units annually by duplicating its hypodermic syringe combination assembly line in the Keene, NH, facility over the next 14 - 16 months.

(b) (4)

3. **Milestones.** To ensure timely delivery of needles and syringes ordered under a new contract with BARDA, Smith's proposes a series of objectively measurable milestones. As indicated below in Volume I, those milestones provide granularity on

the substance and schedule of production and the product delivery contemplated in each of the two overlapping phases. Delivery milestones for Phases I and II will be in months (b) (4) respectively, as indicated in the below capacity chart. These delivery milestones are defined by the month where capacity becomes available to fulfill orders for BARDA.

(b) (4)

- 4. **Deliverables.** To keep BARDA informed of its progress and important developments, Smiths Medical proposes a consistent and measured cadence of reports to the USG. Those reports include quarterly progress reports, semi-annual in-process reviews, an annual financial status report, and a final report.
- 5. **Facilities.** Finally, the Statement of Work found in Volume I provides an overview of key features of its domestic syringe and needle production facility in Keene, NH, including a site overview, product range and capabilities, headcounts, and more.

B. Layout of Design

Established in 1971, the Smiths Medical production facility in Keene, NH, USA, provides assembly and packaging for safety hypodermics, intravenous blood collection, arterial blood sampling, tracheostomy, and pain management kits. It features a range of full and semi-automatic assembly and packaging equipment sets, as well as manual assembly and kitting. The site is 150,000 square feet, including (b) (4) square feet of Cleanroom (Class 8/9) space. The facility is ISO Certified 13485 in Keene, NH. The facility was last audited by the FDA in Oct 2017 & May 2019 receiving no 483 findings from either audit.

1. The Keene, NH, facility product range includes:

- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

2. The Keene, NH, facility employs:

- a. Indirect Headcount (e.g., plant management and support functions): ■ Total full-time employees (FTEs)

- b. Direct Headcount (*e.g.*, production operators): (b) (4) Total FTEs
- c. Temp Headcount: (b) (4) FTEs
- d. Total Headcount: 351 FTEs

3. Facility and Line Layout

The following is the proposed layout of what would be Smiths Medical’s new EDGE™ production line in Keene, NH, including the planned phase two duplication of line.



C. Gantt Chart – Master Schedule

See ATTACHMENT C: Gantt Chart – Master Schedule.

D. Key Project Risks and Mitigation Strategies

1. **Background on Equipment Requirements for Project.** Successful delivery of the project will require sourcing, installation, and validation of assorted equipment including automation / assembly and injection molding equipment. Smiths Medical currently operates 14 global production sites and has a proven track record of large equipment installation and validation. Below is a detailed description of the equipment approach by phase.

a. Phase I Equipment Approach

- i. Additional packaging equipment is to be installed and validated at a different Smiths Medical facility. This new packaging equipment will enable for products to be transferred to other facilities and in turn open additional capacity for hypodermic needles.
- ii. Packaging equipment is extensively utilized at many Smiths Medical facilities and Smiths Medical has extensive experience installing and validating this type of equipment.

b. Phase II Equipment Approach

- i. Duplication of current EDGE™ assembly line in Keene, NH, is required. Smiths Medical proposes to purchase assembly equipment from (b) (4) a previous Smiths Medical supplier, thus generating little design risk.
- ii. Timeline to build equipment of this complexity is typically 14-18 months. Smiths Medical has been in contact with (b) (4) and has begun initial discussions on timeline compression.

c. Known Risks. Timeline for Phase II equipment. (b) (4) will build and deliver automation and assembly equipment. The typical timeline for this equipment is longer than provided for in the proposal. (b) (4) has other COVID-19-related work, which might diminish the company's ability to give preferential treatment to Smiths Medical for the needle and syringe purchases contemplated in the proposed agreement with BARDA.

d. Risk Mitigations. It will be imperative that Smiths Medical, if selected, be authorized to make a definitive purchase from (b) (4) immediately. Additional assistance could be required from BARDA with a rated order and / or supplier incentives for (b) (4). Smiths Medical will actively manage supplier and partner with supplier to expedite / compress schedule as much as possible.

2. Background on Sterilization Requirements for Project. Ethylene Oxide technology is utilized to sterilize all devices included in this proposal. Smiths Medical utilizes two primary 3rd party partners for sterilization: (b) (4). Available capacity within the United States is very constrained due to recent facility closures. Smiths Medical will rely heavily on its current partnerships with (b) (4) to obtain capacity and ensure delivery of devices for this order.

a. Phase I Sterilization Approach

Additional capacity for sterilization will likely come from one of the below options. Smiths Medical anticipates finalizing the determination once a contract is executed with BARDA, largely because the below options are still under investigation and subject to negotiations with suppliers, pending a written agreement from BARDA.

i. (b) (4) [Redacted]

- [Redacted]
- [Redacted]

■ [Redacted]

- [Redacted]
- [Redacted]

b. Phase II Sterilization Approach

Additional capacity for sterilization will likely come from one of the below options. Smiths Medical anticipates finalizing the determination once a contract is signed with BARDA. Beyond the four possibilities below, Smiths Medical will explore additional locations and partnerships to ensure delivery. Please note the below options are still under investigation/negotiations with suppliers pending written agreement with BARDA.

■ (b) (4) [Redacted]

■ [Redacted]

[Redacted]

[Redacted]

[REDACTED]

[REDACTED]

c. **Known Risks.** Lack of sterilization capacity in the United States has been an issue over the last few years, and this risk will continue to grow in severity as elective surgery demand returns and COVID-19 demand continues. Additional capacity will likely require displacing other products in the US from being sterilized as the system is close to capacity. This might include displacing elective or non-essential devices. Sterilizer partners could ask Smiths Medical to reduce other internal requirements to self-balance additional demand, this will not be an option as that will put other critical medical devices at risk of delivery.

d. **Risk Mitigations**

- i. Smiths Medical will actively engage its partners to commit capacity contractually.
- ii. Support from BARDA if required to issue rated orders to partners.
- iii. (b) (4) are undergoing reviews to install additional capacity in the USA; government support/subsidies may be helpful.
- iv. A dedicated sourcing category manager oversees this category daily. Forecast and capacity is reviewed weekly with suppliers. A strong governance structure exists internally to closely monitor sterilization demand and capacity.

3. **Background on Syringe Requirements for Project.** All hypodermics products within the proposal require a syringe. At the moment this component is sourced from 3rd party suppliers. Available capacity within our qualified supply base is extremely limited. Current qualified suppliers are (b) (4). Phase I&II will maximize capacity at [REDACTED] [REDACTED] supplier.

a. **Phase I Syringe Approach**

- i. Capacity will be maximized with the (b) (4) [REDACTED] [REDACTED] Initial capacity can be met by ramping up (b) (4) suppliers to capacity.
- ii. A (b) (4) [REDACTED] will be qualified as risk mitigation, and those qualification activities have already begun.

b. **Phase II Syringe Approach**

- i. Capacity will be further maximized with (b) (4) [REDACTED] design by investing in additional tooling/capacity as needed.
- ii. Additional (b) (4) [REDACTED] design currently undergoing qualification mentioned in 2.a.ii above will be ramped up to capacity.

c. **Known Risks**

- i. Current capacity at approved suppliers will only support Phase I. Additional suppliers and capacity will need to be validated for Phase II.



d. Risk Mitigations

- i. Smiths Medical has existing relationships with many large OEM component manufacturers of syringes and is actively scanning for additional capacity opportunities and partners
- ii. The FDA has provided flexible guidance and has been collaborative in supporting the development and deployment of COVID 19-required products into the field. Smiths Medical proposes to avail itself of those expedited procedures in an effort to expedite FDA review.

VI. VOLUME I

A. Cover Sheet

- 1. BAA Number: MSC-BAA-17-01-W911QY-17-S-0001
Amendment 0003

- 2. Topic Area, as Referenced from the BAA: Section VII.C.2 MEDICAL CHEMICAL
AND BIOLOGICAL
COUNTERMEASURES

- 3. Organization Submitting Proposal: Smiths Medical ASD, Inc.
6000 Nathan Lane North
Minneapolis, MN 55442, USA

- 4. Proposal Title: BARDA/SMITH Medical – Hypodermic
Additional Capacity Proposal

- 5. Interested Points of Contact:

Business:	Technical:
(b) (6)	(b) (6)
(b) (6)	(b) (6)
(b) (6)	(b) (6)
(b) (6)	6000 Nathan Lane N
Smiths Medical	Plymouth, MN 55442
6000 Nathan Lane N	(b) (6)
Plymouth, MN 55442	(b) (6)
(b) (6)	(b) (6)
(b) (6)	(b) (6)
(b) (6)	(b) (6)

- 6. Date Submitted: June 02, 2020
Updated: June 30, 2020 to reflect Phase 1
and Phase 2 Only

B. Content

1. Innovative claims for the proposed effort. This section is the centerpiece of the proposal and should succinctly describe the uniqueness and benefits of the proposed effort and how it fulfills the objectives of the BAA.

Smiths Medical’s innovative devices are well suited to help BARDA achieve the specific BAA objectives identified in the Request for Final Proposal sent to Smiths Medical by BARDA. With the contemplated investment from BARDA, Smiths Medical proposes to (a) leverage product innovations, to (b) support the USG’s overall response to COVID-19, and (c) achieve the specific objectives of this BARDA initiative.

a. (b) (4) [Redacted text block]

[Redacted text block]

b. **Support the USG’s Response to COVID-19.** The USG has a need to procure 600M needle and syringe combination units to vaccinate the US public once a vaccine is identified. Due to the expected vaccine availability, these syringes will be needed as rapidly as possible. To the best of our knowledge, a single source producer alone does not have the capacity to build enough needle and syringe combination units to meet current global demand and US demand created by the need for a COVID-19 vaccine. The USG will need to partner with reputable producers of these needle and syringe combination units to help supplement the goal of procuring 600M units to be used for the vaccine when it becomes available.

The USG also needs to secure these units in a fiscally responsible way, maximizing this proposed overall cost of \$37,205,802 with government investment of \$20,663,774. Smiths Medical, production location in Keene, NH, USA, is proposing a two-overlapping-phased approach to build capacity quickly and achieve a minimum of 110M units and up to 125M+ units through focus on line optimization and duplication of existing equipment for an additional line. The new production will be delivered on a rolling basis, as outlined in (V.3 Technical Proposal – Milestones) above.

- c. **Achieve BARDA’s Project Objectives.** With the contemplated investment from BARDA, Smiths Medical proposes to leverage its product innovations to achieve the objectives of this BARDA initiative, potentially in a manner that helps to reduce overall governmental costs. Specifically, BARDA’s investment will allow Smiths Medical to:
- i. **Expand its existing domestic Continental U.S. (CONUS)-based safety needle and syringe infrastructure and surge capacity** to support response for medical countermeasures, emerging infectious diseases, and other threats of known and unknown origin during a public health emergency;
 - ii. **Increase the throughput** of existing Smiths Medical domestic production capabilities by a minimum of 50% to enable the USG to expedite MCM administration / delivery to meet U.S. COVID-19 MCM demand;
 - iii. Achieve, at a minimum, a throughput added capacity target of **not less than 110 million** safety needle and syringe units; and
 - iv. Provide the USG, through BARDA, **priority access** to facilitate third party purchase of safety needles and syringes produced through this investment effort for COVID-19 medical countermeasures.

Smiths Medical is confident that BARDA’s investment in these innovative products will allow Smiths Medical to be a strong partner in achieving BARDA’s specific objectives for this project. ^[1] For additional information, see ATTACHMENT D: Needle-Pro® EDGE™ Safety Device Deadspace.

2. **Technical rationale, technical approach, and plan for accomplishment of goals and objectives in support of innovative claims and proposed deliverables. Include in this section all proprietary claims to the results, prototypes, intellectual property, or systems supporting and/or necessary for the effort in question. If there are no proprietary claims, this should be stated.**

Smiths Medical is a leading global producer of specialty medical devices that provides innovative and lifesaving solutions for the world’s healthcare markets. Specializing in Infusion Therapy, Vascular Access, Vital Care, and Specialty Products & Services, our products are found in hospital, emergency, home and specialty care environments and are used during critical and intensive care, surgery, post-operative care, and for support in managing chronic illness.

Smiths Medical is one of the global leaders of Vascular Access technology. Within its Vascular Access portfolio, Smiths Medical designs, distributes, and produces medical devices providing healthcare professionals access to patients' vasculature for delivery and withdrawal of fluid and medication, as well as devices to protect health workers by helping prevent needlestick injuries. One of the leading products within this Vascular Access portfolio are the hypodermic needle syringe combinations that are the subject of this proposal.

Smiths Medical produces hypodermic needle syringe combination devices in the (b) (4) facility. This facility has been in production since 1971 and has a proven track record of delivery and quality. The site has a world class staff with on-site automation, engineering, sourcing, planning, and Lean / Continuous Improvement (CI) resources.

When producing hypodermic needle syringe combinations, the site utilizes automated assembly equipment to accomplish this task efficiently and with high quality standards. The plan to achieve our delivery goals is focused around optimizing and expanding our current capacity in two overlapping phases.

To achieve our first delivery in Phase I, Smiths Medical will optimize its current footprint by moving other products produced on this line to other Smiths Medical facilities. The current line is capable and is utilized to produce other configurations and products besides the needle syringe combinations that are the subject of this proposal. By reconfiguring this and other lines, Smiths Medical intends to free up capacity and increase the overall production of needle syringe combinations in a shorter time frame than installing new equipment.

To achieve our second delivery in Phase II, Smiths Medical will need to duplicate its hypodermic needle syringe assembly line in (b) (4). This will be a duplicate of our current line and will be manufactured by the original supplier of the equipment. Utilizing the same supplier minimizes the overall design / development of new equipment and also minimizes any validation / installation risk as the technology is proven. Smiths will also need to expand our current syringe supplier capacity and other components by purchasing duplicate molds. Finally, Smiths Medical will need to qualify and obtain FDA clearance on three new hypodermic needle syringe combinations:

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

These new SKUs will use existing Smiths Medical syringes and needles.

In order to advance this project rapidly, Smiths Medical will concurrently advance activities for project planning, requirements development, detailed design, and prototype production and testing. Following prototype success, Smiths Medical will

advance to design verification and validation testing. Existing assembly and packaging equipment will be utilized for rapidly making these new combinations of needles and syringes for design verification and validation testing. These data will be used to obtain the appropriate FDA 510(k) clearance. Smiths Medical will start the design transfer activities including process validations in parallel to this to minimize the time to launch.⁶

- 3. A clearly defined organization chart for the program team which includes, as applicable: (1) the programmatic relationship of team member; (2) the unique capabilities of team members; (3) the task of responsibilities of team members; (4) the teaming strategy among the team members; and (5) the key personnel to be involved in the effort.**

Below are the key personnel for the proposed project. (b) (6) will be the Senior Program Manager and will lead the internal governance and cadence of the program. As a teaming strategy, (b) (6) will utilize daily, weekly, and monthly check-ins with multiple workstreams to manage all two phases simultaneously. As project sponsor and a member of the Smiths Medical's Senior Leadership Team, (b) (6) will keep the Smiths Medical Senior Leadership Team, including our Chief Executive Officer (b) (6), informed of progress on a regular basis. This project has and will continue to have the full support of and oversight from the Smiths Medical Senior Leadership Team.

Name	Title	Senior Management Program Relationship, Responsibilities, and Tasks	Unique Capabilities
(b) (6)	(b) (6)	Senior project sponsor responsible for overall success of this project.	Member of the Smiths Medical Senior Leadership Team; 30+ years of experience in the medical device industry with a proven track record of timely delivering large-scale projects.
(b) (6)	(b) (6)	Commercial leader and customer service leader; lead contact for BARDA team for day-to-day interactions and inquiries.	Highly experienced corporate account leader with over 20 years in the medical device industry; track record of success at Smiths Medical managing a team calling on large commercial and government organizations with high customer satisfaction.
(b) (6)	(b) (6)	Responsible for all sourcing and 3 rd party requirements of project. Will lead sourcing of syringes, equipment and additional sterilization capacity	Member of Smiths Medical Senior Leadership team. Leads a team of 40 global professionals globally and experienced category managers. Manages and can leverage current Smiths Medical spend of \$400M with strategic partners.
(b) (6)	(b) (6)	R&D Product Line Engineering leader responsible for design control activities	Possesses 15+ years of experience in medical device industry, 12+ years in Vascular Access, with extensive experience in design and development of new products
(b) (6)	(b) (6)	Responsible for all regulatory matters regarding this project. Will lead interactions with FDA as required	A leader in Smiths Medical Regulatory Affairs function with a proven track record successfully gaining FDA clearance for new product introductions.
(b) (6)	(b) (6)	Leader of operations and production at [REDACTED], site; responsible for production planning, execution, quality, and delivery.	Possesses 20+ years of experience in manufacturing and operations; extensive experience in leading projects to install and improve manufacturing lines.
(b) (6)	(b) (6)	Program manager responsible for managing overall timeline; will ensure workstreams for each phase are on track, and in case of roadblocks/challenges, will quickly escalate and resolve.	Possesses 30+ years in medical device industry with extensive manufacturing and program management experience.

Additionally, Attachment H outlines the program team organization assigned to the capacity expansion project with CV's as Attachment I.

4. Discussion concerning any potential likelihood to leverage the effort for use among other Government organizations of interest if/as may be appropriate, along with any details concerning current use by other non-federal parties.

Currently, the U.S. demand is satisfied outside of the current COVID-19 situation and does not require Smiths Medical to add additional production capacity. Due to cost, customers outside the United States (OUS) predominantly use non-safety devices, so it is unlikely additional capacity would be used OUS. However, the capacity expansion would be available for Strategic National Stockpile restocking and for future pandemic assistance within the United States.

5. Statement of Work (SOW) :

a. The objective of the proposed project.

Consistent with the objectives articulated by BARDA in its Request for Final Proposal to Smiths Medical, our objectives for this proposal are fourfold: **(i)** To support the U.S. Federal Government's (USG) efforts to expand existing domestic Continental US (CONUS) based safety needle and syringe infrastructure and surge capacity to support response for medical countermeasures, emerging infectious diseases and other threats of known and unknown origin during a public health emergency; **(ii)** to increase the throughput of existing domestic production capabilities by a minimum of 50% to enable the USG to expedite MCM administration/delivery to meet US COVID-19 MCM demand; **(iii)** to achieve, at a minimum, a throughput target of an added capacity of not less than **(b) (4)** safety needle and syringe units; and **(iv)** to provide the USG, through BARDA, priority access to facilitate third party purchase of safety needles and syringes produced through this investment effort for COVID-19 medical countermeasures through BARDA's existing contract with Marathon Medical.

b. A detailed description of the approach to be taken to accomplish the stated objective.

Smiths Medical proposes to assist BARDA in achieving its stated objective of increasing production capacity and delivering safety needles and syringes to meet increased MCM demand for COVID-19 response. The approach Smiths Medical will take includes two overlapping phases, to be commenced simultaneously upon execution of an agreement between BARDA and Smiths Medical. We broke the projects into two phases to help create transparency and drive accountability. Below is a brief description of the phases of the projects Smiths Medical will initiate.

Phase	Description	Timeline	Capacity
I	<ul style="list-style-type: none"> Qualify new packaging line in alternate Smiths Medical site; Transfer non-hypodermic syringe combination devices to alternate Smiths Medical site; Dedicate capacity to safety needle syringe combination devices; and Procure additional tooling at suppliers to increase component capacity. 	7 - 9 months from executed agreement	(b) (4) annually
II	<ul style="list-style-type: none"> Procure equipment and duplicate EDGE™ assembly line in (b) (4) and Develop, qualify, and receive FDA clearance for three new SKUs.¹ 	14 - 16 months from executed agreement	(b) (4) annually

Smiths Medical has dedicated resources to project teams and begun initial preparations. As indicated above, a management structure has been created to ensure project teams have the necessary resources, the authority to make decisions, and a path for escalations and resolutions. Operating mechanisms (patterned project meetings, steering committee meetings, and the like) have been established to ensure progress and quick resolution to issues that may impede progress.

c. The measurable milestones involved & associated completion criteria for each involved.

i. Phase I: Duration 7-9 Months

Upon final completion of the tasks below in Phase I, SM will be able to deliver up to an additional (b) (4) combined needle and syringe units per month.

Task Name	Duration
Phase I: Line Optimization & Tooling	
(b) (4)	

d. All deliverables (reporting, data, reports, etc.) to be provided to the Government in support of the proposed tasks/activities.

- i. Quarterly Progress Reports.** Submitted quarterly no later than the 10th calendar day of the quarter. Contractor format acceptable. Electronic submission acceptable in MS Office or PDF format. Financial information shall be MS Excel format. Quarterly reports shall NOT be marked proprietary, and shall have Distribution Statement C (US Government and their contractors). Each quarterly report shall, at a minimum, contain the following:
 - a.** Summary of quarterly progress for each of the recipient’s facilities/capabilities associated with this effort.
 - b.** Summary of progress towards established milestones for each facility/capability.
 - c.** Identification of any milestone that is slipping or missed, and discussion of path forward to bring milestone back to schedule, and impact on other milestones.
 - d.** Summary of risks, discussion of potential impacts and efforts to mitigate.
 - e.** Summary of overall schedule and changes from previous quarter.
 - f.** Financial summary of recipient costs incurred by quarter to date, invoices submitted, and Government payments made.

- ii. Semi-Annual In-Process Reviews.** Scheduled as needed, generally not more frequently than semi-annually, at the recipient’s facilities. Duration: 8 hrs. max. Face to face review of previous two quarters’ activities. Informative in nature to keep BARDA apprised of project progress and to discuss issues that may require joint resolution, such as milestone changes, political impacts on objectives, schedule, funding.

- iii. Annual Financial Status Report.** See ALIN 4000.

e. Description of the facilities that would be used for the proposed effort.

Established in 1971, the Smiths Medical production facility in (b) (4) USA, provides assembly and packaging for safety hypodermics, intravenous blood collection, arterial blood sampling, tracheostomy and pain management kits. It features a range of full and semi-automatic assembly and packaging equipment sets, as well as manual assembly and kitting. The site is [REDACTED] square feet, including (b) (4) square feet of Cleanroom (Class 8/9) space. The facility is ISO Certified 13485 in (b) (4)

i. The (b) (4) facility product range includes:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

(b) (4) [Redacted]

ii. The (b) (4) facility employs:

(b) (4) [Redacted]

f. Capital and Commercial equipment to be purchased to achieve the proposed objective.

- i. **Phase I.** To achieve our first delivery in Phase I, Smiths Medical will optimize its current footprint by moving other products produced on this line to other Smiths Medical facilities. The current line is capable and is utilized to produce other configurations and products besides the needle syringe combinations that are the subject of this proposal. By reconfiguring this and other lines, Smiths Medical intends to free up capacity and increase the overall production of needle syringe combinations in a shorter time frame than installing new equipment. For additional detail, see the following table.

(b) (4)

*Long lead item. In effort to meet the timelines contained herein, Smiths Medical submitted the order for this equipment prior to receipt of award. Above does not include Capital Equipment Overhead. (See 24 June 2020 Smiths Medical BARDA RFFP Financials v4)

- ii. **Phase II.** To achieve the second delivery in Phase II, Smiths Medical will need to duplicate its hypodermic needle syringe assembly line in (b) (4) [Redacted]. This will be a duplicate of Smiths Medical' current line and will be produced by the original supplier of the equipment. Utilizing the same supplier minimizes the overall design / development of new equipment and also minimizes any validation / installation risk as the technology is

■

Functional Abbreviations		
Ops	Site QE	Site Quality Engineering
	Site ME	Site Manufacturing Engineering
	AME	Operations: Advanced Manufacturing Engineering
	GLS	Operations: Global Sourcing
	LBL	Global Labeling
	MFE	Manufacturing Engineering
	SCN	Supply Chain Planning
	SQE	Supplier Quality Engineering
	MICROBIO	Microbiology
R&D	FUNCT ME	R&D Functional Engineering Mechanical Engineering
	PENG	Packaging Engineering
	PLE	Product Line Engineering
	TOX	Biocompatibility/Toxicology
GQR	QOM	Quality Operations - Microbiology
	DAS	Design Assurance
	Tech Comm	Technical Communications
	RAF	Regulatory Affairs
Misc.	FIN	Finance
	PM	Project/ Program Manager
	GPM	Global Product Management

VII. VOLUME II

A. Cover Sheet

1. BAA Number: MSC-BAA-17-01-W911QY-17-S-0001
Amendment 0003
2. Topic Area, as Referenced from the BAA: Section VII.C.2 MEDICAL CHEMICAL
AND BIOLOGICAL
COUNTERMEASURES
3. Organization Submitting Proposal: Smiths Medical ASD, Inc.
6000 Nathan Lane North
Minneapolis, MN 55442, USA
4. Proposal Title: BARDA/SMITH Medical – Hypodermic
Additional Capacity Proposal
5. Interested Points of Contact:
- | Business: | Technical: |
|--------------------|--------------------|
| (b) (6) | (b) (6) |
| (b) (6) | (b) (6) |
| (b) (6) | (b) (6) |
| (b) (6) | 6000 Nathan Lane N |
| Smiths Medical | Plymouth, MN 55442 |
| 6000 Nathan Lane N | (b) (6) |
| Plymouth, MN 55442 | (b) (6) |
| (b) (6) | (b) (6) |
| (b) (6) | (b) (6) |
| (b) (6) | (b) (6) |
6. Date Submitted: June 02, 2020
Updated: June 30, 2020 to reflect Phase I
and Phase II Only
7. CAGE Code: 52087
8. DUNS Number: 056329097
9. Name, address, and phone number of
administration (DCMA) office: N/A
10. Name, address, and phone number of
audit (DCAA) office N/A: N/A
11. Is this proposal consistent with your established estimating and accounting practices &
procedures? If no, explain: Yes

B. Content

This financial volume provides data in sufficient detail to substantiate the reasonableness of the funding. All calculations and formulas are included with this financial information. The breakdowns herein include total requested funding, inclusive of all major cost items.

All spend for this project outside of Smiths Medical (*e.g.*, equipment, materials, and other direct costs) will go through Smiths Medical sourcing/procurement process/governance. Smiths Medical on a yearly basis procures (b) (4) of spend through third party sources. All of this spend goes through a robust governance and source-to-pay process. Smiths Medical has a procurement organization with (b) (4) sourcing professionals who on a daily basis ensure all 3rd party spend has proper quality, delivery, and cost. (b) (6) of Global Sourcing, will be a key leader of this project and will oversee the success of all supplier interdependencies for this project. He is a part of the Smiths Medical Senior Leadership Team and will bring the support of senior leadership as needed.

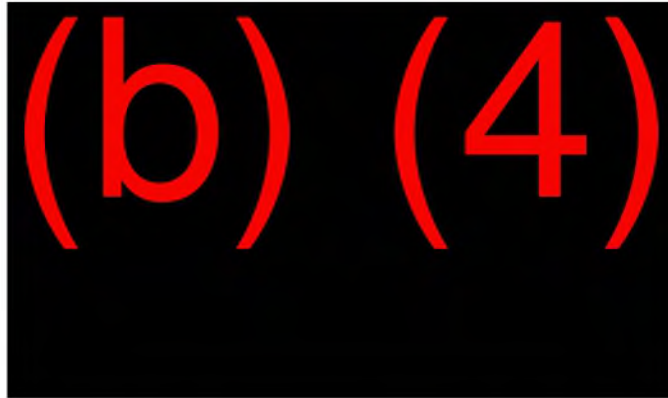
1. Direct Labor – including individual labor categories with associated labor hours and direct labor rates.

The total direct labor cost for the project is (b) (4). To simplify this proposal, we have taken an average direct labor rate of (b) (4) which is a volume weighted average direct labor rate for the resources required. We have laid out staffing requirements by function and phase in the below table, which may also be found at ATTACHMENT F: Direct Labor Cost Table. You can also find a functional abbreviation summary to decode the functional resources required from the summary.

(b) (4)

2. Indirect Costs – Including Fringe Benefits, Overhead, General and Administrative (G&A) Expense, Cost of Money, Fee, etc. (must show base amount and rate).

The total indirect cost for all phases of this project is (b) (4). This is calculated by utilizing Smith Medical's corporate indirect burden rate of (b) (4) on top of our (b) (4) labor rate from section 2. A table of the breakdown of the burden rate of (b) (4) is included below.



- 3. Subcontractors – List all subcontractors. For each subcontractor, include total subcontract cost and build-out for all direct labor, indirect costs, travel, materials, and other direct costs. For each subcontractor, include a worksheet in the Excel workbook that breaks out proposed subcontract cost with a similar level of detail proposed by the recipient.**

At this time, no subcontractors are planned to be utilized for this project. If Smiths Medical does require subcontractors, it will be in lieu of SM employees detailed above in Volume II section B.2.

- 4. Travel – Provide the purpose of the trip, number of trips, number of days per trip, departure and arrival destinations, number of people, etc.**

Due to the company's COVID-19 policy, air travel will likely be minimal during this project. The project team includes local support in (b) (4) to ensure no impact to timeline from these restrictions. Any air travel expenses by Smiths Medical personnel will be covered by Smiths Medical and is already included within our G&A burden rate.

- 5. Other Direct Costs (ODCs) – Itemized by cost category, with sufficient backup documentation to support proposed costs. Below find our current best estimates.**

Other direct costs will total (b) (4) and include:

- a. Rigging and facilities cost to enable installation of new equipment;
- b. Contingency for transportation & other likely required testing such as biocompatibility and drug testing
- c. Validation of new cycles / chambers at sterilizers to expand capacity
- d. Facility expansion costs

Estimates for ODCs are built based on reviewing similar past projects, preliminary quotes and estimation from subject matter experts.

(b) (4)

6. **Equipment Purchases – Itemized list with associated costs, including quantities, unit prices, proposed vendors (if known), and the basis of estimate *e.g.*, quotes, prior purchases, catalog price lists, etc.); any item that exceeds \$10,000 must be supported with back-up documentation such as a copy of catalog price lists or quotes prior to purchase.**

Equipment required to execute Phases I - II includes assembly automation equipment and injection molding molds. The total estimated equipment cost for all two phases is

(b) (4)

To estimate equipment cost, Smiths Medical has reviewed: (a) quotes for similar equipment purchased in the past; and (b) preliminary quotes received from vendors for a portion of the equipment required for this project.

Smiths Medical routinely buys this type of equipment and has partnerships with multiple automation and tooling suppliers. Quotes will be competitively analyzed before approved.

All equipment spend will follow Smiths Medical Capital Equipment purchasing process DOC # B10001875 , details of the process can be found in Appendix G.

- a. **Equipment Cost Summary by Phase:**

(b) (4)

(b) (4)

8. The source, nature, and amount of proposed cost-sharing.

As mentioned previously, Smiths Medical’s (b) (4) facility has the physical space to house an additional production line that can ultimately produce an additional (b) (4) units annually. Currently, we do not have the commercial business to justify installing additional production capacity. That said, Smiths Medical recognizes the need to develop U.S. production capability and a readiness posture to address potential future pandemics and outbreaks. Our proposal takes into account that hypodermics are highly commoditized with low margins and there will be a cost to maintain and keep line operational for future pandemic readiness.

With this in mind, we propose the following cost-sharing on behalf of Smiths Medical in exchange for a total capacity investment of (b) (4) and assumes a 10-year useful life:

Total Amount of Government Funding for the Agreement: (b) (4)
 Total Smiths Medical Cost Share for the Agreement: (b) (4)
 Total Estimated Value of the Agreement: (b) (4)

Note: Please see .xlsx “24 June 2020 Smiths Medical BARDA RFFP Financials V4” for further details.

Additionally, we will offer a (b) (4) discount value on any USGov/BARDA directed purchases for a pandemic or public health emergency for up to (b) (4) units on the new capacity providing additional value of (b) (4)

Illustration Purposes:

Units available for discount up to (b) (4) needle and syringe combinations on new capacity	Based on Current \$/unit	Needle and Syringe \$ Spend	N&S Discount for any USGov/BARDA directed purchases for a pandemic or public health emergency	Estimated Value
(b) (4)				

VIII. ADDITIONAL PROVISIONS

- A. Confidentiality.** This document and ATTACHMENTs contain confidential and proprietary commercial and trade secret information that is protected from public disclosure under the Federal Food, Drug, and Cosmetic Act, the Freedom of Information Act, FDA's implementing regulations, and the Trade Secrets Act. If a request for disclosure is received, the Company requires that it be notified and provided an opportunity to address why the information or materials should not be released or, in the event that the applicable government agency determines that documents or materials containing such confidential or proprietary information should be released, the Company requests that it be permitted to perform appropriate redactions.
- B. Intellectual Property.** Pre-existing proprietary and confidential property, including patented, copyrighted and trademarked property, of Smiths Medical and its third-party suppliers is and shall remain the property of Smiths Medical and its third-party suppliers. Any and all materials, designs, or other intellectual property created, developed, or reduced to practice by Smiths Medical in connection with the work performed under an awarded contract, including designs, inventions, works of authorship, prototypes, and processes (the "Work Product") will remain the property of the Smiths Medical. The Government shall acquire no rights in the above-referenced property, including but not limited to any licenses to use, modify, or create derivative works. The Government shall not share such information with third parties without specific written permission of Smiths Medical or its relevant third-party supplier.
- C. Non-Binding Proposal.** Submission of this proposal by Smiths Medical does not in any way constitute an offer to enter into a contract, or otherwise perform or render any services or products as part of a contract, obligating either Smiths Medical or the Government. The Government's acceptance of this proposal shall only constitute an invitation by the Government to enter into formal negotiations with Smiths Medical to seek to enter into a legally binding contract to perform the services and produce the products for purchase by the Government described in the proposal.

IX. FOOTNOTE REFERENCES

1. ATTACHMENT B: EDGE™ Safety Hypodermic Devices
2. ATTACHMENT D: Needle-Pro® EDGE™ Safety Device Deadspace
3. <https://www.cdc.gov/vaccines/hcp/infographics/ycts-flu.html>
4. <http://www.infectioncontrolday.com/news/2013/08/prevention-of-needlestick-injuries-can-save-us-healthcare-system-more-than-1-billion-annually.aspx>
5. <http://www.nytimes.com/2016/03/01/health/waste-in-cancer-drugs-costs-3-billion-a-year-a-study-says.html>
6. While our experience leads to high confidence in obtaining all required clearances, some of the products described in this proposal are or will be under development by Smiths Medical and are subject to FDA 510(k) Premarket Notification clearance prior to commercial distribution. Smiths Medical makes no definitive claims about the final features and benefits of products which are not yet FDA cleared. Any discussions related to products in development are solely for the purpose of providing information relating to the potential development project proposed herein. Smiths Medical is not prepared to nor may it take orders for any products mentioned in this proposal that are not yet FDA cleared or where a 510(k) Premarket Notification clearance is pending.
7. See Section VIII (B) Intellectual Property.
8. ATTACHMENT A: EDGE™ Product Summary

B. Agreement

B.1. The Government intends to award up to one (1) Technology Investment Agreement (TIA) or Grants to Smiths Medical in response to this solicitation, which is issued under Broad Agency Announcement MSC-BAA-17-01-W911QY-17-S-0001 Amendment 0003, Section VII.C.2 MEDICAL CHEMICAL AND BIOLOGICAL COUNTERMEASURES.

B.2. If a TIA is awarded as a result of this solicitation, it will be executed under the authority 10 USC 2371 - Research Projects other than contracts and grants, which requires cost sharing between the Government and recipient. The expenditure-based TIA cost sharing ratio shall begin with a 50/50 Government/Awardee share ratio. The recipient's cost share comprised of allowable project investment costs including, but not limited to in-house labor and subcontracted costs, equipment utilization and capital equipment costs incurred by the recipient in achieving the objectives of this effort. See 32 CFR 37.215(b).

B.6. Agreement Line Items (ALIN)

ALIN 1000: Development/Expansion of manufacturing capacity for hypodermic safety needles and corresponding syringes in accordance with the Statement of Objectives outlined in Section C below.

ALIN 2000: Monthly progress reports. 2001, 2002, 2003 etc.

ALIN 3000: Quarterly In-Process Reviews (IPR) Hosted at the recipient's facilities. 3001, 3002, 3003 etc.

ALIN 4000: Annual Financial Status Report

ALIN 5000: Final Report that details the findings and issues of the completed project.

C. Statement of Objectives

C.1. Introduction.

C.2. General Objectives.

The recipient shall expand existing domestic Continental US (CONUS) based safety needle and syringe infrastructure and surge capacity to support response for medical countermeasures, emerging infectious diseases and other threats of known and unknown origin during a public health emergency. In the event that existing capacity is unavailable, the recipient shall identify, develop and qualify new US-based manufacturing for utilization with USG (BARDA and affiliate partners) MCMs. In the event of the declaration of a public health emergency, the recipient shall provide priority access to this new or existing MCM capacity for BARDA and other Federal agencies authorized by BARDA. Expansion of existing domestic capacity shall be through accelerated expansion of assembly lines, molding lines, packaging lines, tooling and any other related manufacturing capabilities in existing recipient facilities.

C.3. Specific Objectives.

C.3.1. The recipient shall increase the throughput of existing domestic manufacturing capabilities by a minimum of 50% to enable the USG to expedite MCM administration/delivery to meet US COVID-19 MCM demand. Expansion/development sites include, but are not limited to:

- Expansion safety needle and syringe manufacturing capacity in Keene, NH

C.3.2. The minimum throughput target for Smiths Medical's needle and syringe manufacturing capabilities is defined as achieving an added capacity of not less than 110 million safety needle and syringe units.

C.3.3. Upon completion of the effort, the USG, through BARDA, shall receive priority access to facilitate third party purchase of safety needles and syringes produced through this investment effort for COVID-19 medical countermeasures.

C.4. Schedule Objectives.

The schedule for this effort shall be from date of award (anticipated June 2020) through August 30, 2021. Incremental capacity will become available quarterly beginning in 2021. However, more rapid acceleration is highly desired by the Government in order to meet critical COVID-19 response needs. As acceleration opportunities are identified, the recipient is encouraged to work with USG BARDA to make optional incremental funding to realize these opportunities. As incremental capabilities become available from different component facilities, they shall be placed online as quickly as possible and made available to USG BARDA to meet critical national COVID-19 demands.

C.5. Overall Management Objectives.

The recipient shall be responsible for overall management and oversight of the work necessary to achieve the objectives of this agreement. The recipient shall provide the overall management, integration, and coordination of all agreement activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all agreement activities.

The recipient shall establish project milestones for each facility/capability for which expansion and/or development is planned. Incremental progress against each milestone shall be provided to BARDA in accordance with established deliverables (see C.9 below). Any changes or deviations planned or incurred by the recipient in pursuing the objectives of this agreement shall be reported to BARDA. While primary responsibility for management and execution of the effort resides with the recipient, BARDA shall have input to the milestone review process and any changes to the objectives of the agreement. BARDA shall have the responsibility for communicating to the recipient any changes in USG MCM strategies that may impact this agreement.

C.6. Risk Management Objectives.

The recipient shall identify all anticipated project risks categorized as moderate or high and report them to BARDA in accordance with reporting requirements (see C.9 below). The recipient shall manage all project risks using its in-house risk management capabilities, and report to BARDA changes to all identified risks as they occur/arise. BARDA shall be permitted to participate in the risk management and mitigation processes associated with this project.

C.7 Physical Property.

Title to all physical property developed under this Agreement shall vest with Smiths Medical.

C.8. Intellectual Property.

Intellectual Property rights for all technology developed under this agreement shall reside with Smiths Medical, with the exception of information contained in specified deliverables, which shall be subject to distribution within US Government agencies and their contractors (Distribution Statement C). See C.9 below.

C.9. Deliverables.

C.7.1. Monthly Progress Reports. See ALIN 2000. Submitted monthly no later than the 10th of the month. Contractor format acceptable. Electronic submission acceptable in MS Office or PDF format. Financial information shall be MS Excel format. Monthly reports shall NOT be marked proprietary, and shall have Distribution Statement C (US Government and their contractors). Each monthly report shall, at a minimum, contain the following:

- Summary of monthly progress for each of the recipient's facilities/capabilities associated with this effort.
- Summary of progress towards established milestones for each facility/capability.
- Identification of any milestone that is slipping or missed, and discussion of path forward to bring milestone back to schedule, and impact on other milestones.
- Summary of risks, discussion of potential impacts and efforts to mitigate.
- Summary of overall schedule and changes from previous month.
- Financial summary of recipient costs incurred by month to date, invoices submitted, and Government payments made.

C.7.2. Quarterly In Process Reviews. See ALIN 3000. Scheduled as needed, generally not more frequently than quarterly, at the recipient's facilities. Duration: 8 hrs max. Face to face review of previous quarter's activities. Informative in nature to keep BARDA apprised of project progress and to discuss issues that may require joint resolution, such as milestone changes, political impacts on objectives, schedule, funding.

C.7.3. Annual Financial Status Report. See ALIN 4000

C.7.4. Final Report. See ALIN 5000. Final Report shall NOT be marked proprietary, and shall have Distribution Statement C. Final report summarizing stated objectives and the progress that was achieved in meeting those objectives; summary of risks incurred, impacts and mitigation; quantitative discussion of needle and syringe production throughput improvements achieved; financial summary of project; schedule summary for project, comparing original schedule to final schedule; recommendations for path forward as applicable.

ID	Task Mode	Task Name	Duration	Start	Finish	Predecessor	Quarter	3rd Quarter	1st Quarter	3rd Quarter	1st Quarter	
							Mar	May	Jul	Sep	Nov	Jan
1		BARDA/SMITH Medical - Hypodermic Additional Capacity										



Project: BARDA Master Schedu Date: Tue 6/30/20	Task		Inactive Summary		External Tasks	
	Split		Manual Task		External Milestone	
	Milestone		Duration-only		Deadline	
	Summary		Manual Summary Rollup		Critical	
	Project Summary		Manual Summary		Critical Split	
	Inactive Task		Start-only		Progress	
	Inactive Milestone		Finish-only		Manual Progress	

ID	Task Mode	Task Name	Duration	Start	Finish	Predecessor	Quarter	3rd Quarter	1st Quarter	3rd Quarter	1st Quarter	
							Mar	May	Jul	Sep	Nov	Jan

(b) (4)

Project: BARDA Master Schedu Date: Tue 6/30/20	Task		Inactive Summary		External Tasks	
	Split		Manual Task		External Milestone	
	Milestone		Duration-only		Deadline	
	Summary		Manual Summary Rollup		Critical	
	Project Summary		Manual Summary		Critical Split	
	Inactive Task		Start-only		Progress	
	Inactive Milestone		Finish-only		Manual Progress	

ID	Task Mode	Task Name	Duration	Start	Finish	Predecessor	Quarter	3rd Quarter	1st Quarter	3rd Quarter	1st Quarter								
							Mar	May	Jul	Sep	Nov	Jan	Mar	May	Jul	Sep	Nov	Jan	Mar

(b) (4)

Project: BARDA Master Schedu
Date: Tue 6/30/20

Task		Inactive Summary		External Tasks	
Split		Manual Task		External Milestone	
Milestone		Duration-only		Deadline	
Summary		Manual Summary Rollup		Critical	
Project Summary		Manual Summary		Critical Split	
Inactive Task		Start-only		Progress	
Inactive Milestone		Finish-only		Manual Progress	

ID	Task Mode	Task Name	Duration	Start	Finish	Predecessor	Quarter	3rd Quarter	1st Quarter	3rd Quarter	1st Quarter								
							Mar	May	Jul	Sep	Nov	Jan	Mar	May	Jul	Sep	Nov	Jan	Mar

(b) (4)

Project: BARDA Master Schedu Date: Tue 6/30/20	Task		Inactive Summary		External Tasks	
	Split		Manual Task		External Milestone	
	Milestone		Duration-only		Deadline	
	Summary		Manual Summary Rollup		Critical	
	Project Summary		Manual Summary		Critical Split	
	Inactive Task		Start-only		Progress	
	Inactive Milestone		Finish-only		Manual Progress	

BARDA Security Requirements--SOP

The following paragraphs are the minimum-security requirements for any partner facility receiving a BARDA contract where the USG purchases product or technologies.

Table 1: BARDA Security Requirements	
1. Security Administration	
Security Program	The partner facility shall have a comprehensive security program that provides a security plan for the overall protection of personnel, information, data, and facilities associated with fulfilling the BARDA requirement. The proposal submitted shall include a security plan which establishes security practices and procedures that demonstrate how the Offeror will meet and adhere to the security requirements outlined below prior to the commencement of product manufacturing. The Offeror shall also ensure that other entities (sub-contractors, consultants, etc.) performing work on behalf of the Offeror establishes and manages a security program that complies with all BARDA security requirements.
2. Facility Security Plan	
As part of the partner facility's overall security program, the Offeror shall submit a written security plan with their proposal to BARDA for review and approval by BARDA security subject matter experts. The performance of work under the BARDA contract will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:	
Security Administration	Organization chart and responsibilities; written security risk assessment for site; threat levels with identification matrix (High, Medium, or Low); enhanced security procedures during elevated threats; liaison procedures with law enforcement; annual employee security education and training program.
Personnel Security Policies and Procedures	Candidate recruitment process; background investigations process; employment suitability policy; employee access determination; rules of behavior/ conduct; termination procedures; non-disclosure agreements.

Table 1: BARDA Security Requirements

Physical Security Policies and Procedures	Internal/external access control; protective services; identification/badging; employee and visitor access controls; parking areas and access control; perimeter fencing/barriers; product shipping, receiving and transport security procedures; facility security lighting; restricted areas; signage; intrusion detection systems; alarm monitoring/response; closed circuit television; product storage security; other control measures.
Information Security	Identification and marking of sensitive information; access control; storage of information; document control procedures; retention/ destruction requirements.
Information Technology/Cyber Security Policies and Procedures	Intrusion detection and prevention systems; threat identification; employee training (initial and annual); encryption systems; identification of sensitive information/media; password policy (max days 90); lock screen time out policy (minimum time 20 minutes); removable media policy; laptop policy; removal of IT assets for domestic/foreign travel; access control and determination; VPN procedures; WiFi and Bluetooth disabled when not in use; system document control; system backup; system disaster recovery; incident response; system audit procedures; property accountability.

3. Site Security Master Plan

	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.
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4. Site Threat / Vulnerability / Risk Assessment

	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.
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5. Physical Security

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.
---	--

Table 1: BARDA Security Requirements

	<ul style="list-style-type: none">(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.
Facility Lighting	<ul style="list-style-type: none">(a) Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings.(b) Lighting must have emergency power backup.(c) Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.
Shipping and Receiving	<ul style="list-style-type: none">(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 BARDA products by government issued photo identification.
Access Control	<ul style="list-style-type: none">(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 12 months.(f) Must have procedures in place to track issuance of access cards to employees and the ability to deactivate cards when they are lost or an employee leaves the company.(g) Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of 12 months.

Table 1: BARDA Security Requirements

	<p>(h) Should have written procedures to prevent employee piggybacking.</p> <p>(i) Access to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access.</p> <p>(j) Must have a written manual key accountability and inventory process.</p> <p>(k) Physical access controls should present a layered approach to critical assets within the facility.</p>
Employee/Visitor Identification	<p>(a) Should issue company photo identification to all employees.</p> <p>(b) Photo identification should be displayed above the waist anytime the employee is on company property.</p> <p>(c) Visitors should be sponsored by an employee and must present government issued photo identification to enter the property.</p> <p>(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.</p>
Security Fencing	Requirements for security fencing will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces	Requirements for security officers will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces Operations	<p>(a) Must have in-service training program.</p> <p>(b) Must have Use of Force Continuum.</p> <p>(c) Must have communication systems available (i.e., landline on post, cell phones, handheld radio, and desktop computer).</p> <p>(d) Must have Standing Post Orders.</p> <p>(e) Must wear distinct uniform identifying them as security officers.</p>

6. Security Operations

Table 1: BARDA Security Requirements

Information Sharing	<p>Establish formal liaison with law enforcement.</p> <p>(a) Meet in person at a minimum annually. Document meeting notes and keep them on file for a, minimum of 12 months. POC information for LE Officer that attended the meeting must be documented.</p> <p>(b) Implement procedures for receiving and disseminating threat information.</p>
Training	<p>(a) Conduct new employee security awareness training.</p> <p>(b) Conduct and maintain records of annual security awareness training.</p>
Security Management	<p>(a) Designate a knowledgeable security professional to manage the security of the facility.</p> <p>(b) Ensure subcontractor compliance with all BARDA security requirements.</p>

7. Personnel Security

Records Checks	<p>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.</p>
Hiring and Retention Standards	<p>(a) Detailed policies and procedures concerning hiring and retention of employees, employee conduct, and off boarding procedures.</p> <p>(b) Off Boarding procedures should be accomplished within 24 hour of employee leaving the company. This includes termination of all network access.</p>

8. Information Security

Physical Document Control	<p>(a) Applicable documents shall be identified and marked as procurement sensitive, proprietary, or with appropriate government markings.</p> <p>(b) Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet/desk or other storage device and not be left unattended.</p>
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Table 1: BARDA Security Requirements

	(c) Access to sensitive information should be restricted to those with a need to know.
Document Destruction	Documents must be destroyed using approved destruction measures (i.e., shredders/approved third party vendors / pulverizing / incinerating).

9. Information Technology & Cybersecurity

Identity Management	<p>(a) Physical devices and systems within the organization are inventoried and accounted for annually.</p> <p>(b) Organizational cybersecurity policy is established and communicated.</p> <p>(c) Asset vulnerabilities are identified and documented.</p> <p>(d) Cyber threat intelligence is received from information sharing forums and sources.</p> <p>(e) Threats, vulnerabilities, likelihoods, and impacts are used to determine risk.</p> <p>(f) Identities and credentials are issued, managed, verified, revoked, and audited for authorized devices, users and processes.</p> <p>(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)</p>
Access Control	<p>(h) Limit information system access to authorized users.</p> <p>(i) Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access.</p> <p>(j) Limit physical access to information systems, equipment, and server rooms with electronic access controls.</p>
Training	Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.
Audit and Accountability	(a) Create, protect, and retain information system audit records to the extent needed to enable the monitoring, analysis, investigation, and reporting of

Table 1: BARDA Security Requirements

	<p>unlawful, unauthorized, or inappropriate system activity. Records must be kept for minimum must be kept for 12 months.</p> <p>(b) Ensure the actions of individual information system users can be uniquely traced to those users.</p>
Configuration Management	Establish and enforce security configuration settings.
Contingency Planning	Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times.
Incident Response	Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery of cybersecurity incidents. Exercise this capability annually.
Media and Information Protection	<p>(a) Protect information system media, both paper and digital.</p> <p>(b) Limit access to information on information systems media to authorized users.</p> <p>(c) Sanitize and destroy media no longer in use.</p> <p>(d) Control the use of removable media through technology or policy.</p>
Physical and Environmental Protection	<p>(a) Limit access to information systems, equipment, and the respective operating environments to authorized individuals.</p> <p>(b) Intrusion detection and prevention system employed on IT networks.</p> <p>(c) Protect the physical and support infrastructure for all information systems.</p> <p>(d) Protect information systems against environmental hazards.</p>
Network Protection	Employ intrusion prevention and detection technology with immediate analysis capabilities.

Table 1: BARDA Security Requirements

10. Transportation Security

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

Drivers	<ul style="list-style-type: none">(a) Drivers must be vetted in accordance with BARDA 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 BARDA product.(e) Drivers must never leave BARDA products unattended, and two drivers may be required for longer transport routes or critical products during times of emergency.(f) Truck pickup and deliveries must be logged and kept on record for a minimum of 12 months.
Transport Routes	<ul style="list-style-type: none">(a) Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency.(b) Transport routes should be continuously evaluated based upon new threats, significant planned events, weather, and other situations that may delay or disrupt transport.
Product Security	<ul style="list-style-type: none">(a) BARDA products must be secured with tamper resistant seals during transport, and the transport trailer must be locked and sealed.(b) Tamper resistant seals must be verified as "secure" after the product is placed in the transport vehicle.(a) BARDA products should be continually monitored by GPS technology while in transport, and any deviations from planned routes should be investigated and documented.(b) Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.

Table 1: BARDA Security Requirements

11. Security Reporting Requirements

The partner facility shall notify the BARDA Security Team within 24 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of government products. The facts and circumstances associated with these incidents will be documented in writing for government review.

12. Security Audits

The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and subcontractor locations. Minimum length of notification is 10 business day.

ATTACHMENT E
Financial Worksheet

Year 1 (Jun '20 - May '21)

Year 2 (Jun '21 - May '22)

Year 3-10 (Jun '22 - May '29)

(b)

(4)

Government Share of Cost*

(b) (4)

(b) (4) *ov Cost Share Overall*

*Note:

(b) (4)

(b) (4)

ATTACHMENT F

Direct Labor Cost

		Labor Staffing Estimates by phase by workstream (100%=1 dedicated FTE)																							
Phase	Work Stream	Duration (MONTHS)	Direct labor rate	Indirect burden markup	Billable indirect rate	Ops							R&D				GQR			OTHER				FTEs/Months	Total Cost (assumes 173 hours per month per FTE)
						Site QE	Site ME	AME	GLS	LBL	IME	SCN	SQE	MICROBIO	FUNCT ME	PENG	PLE	TOX	QOM	DAS	Tech Comm	RAF	FIN		

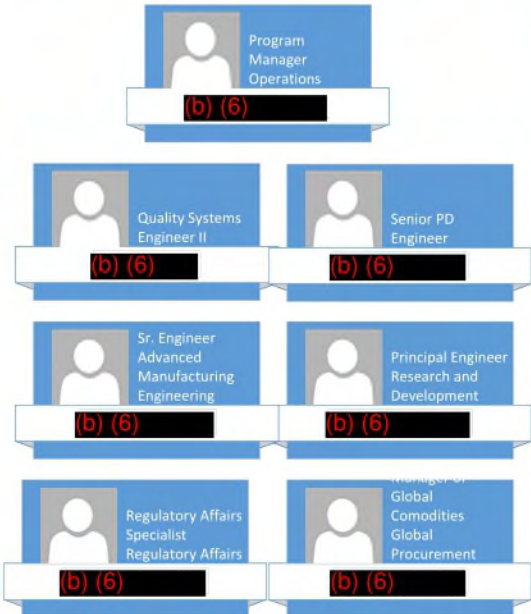
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Functional Abbreviations

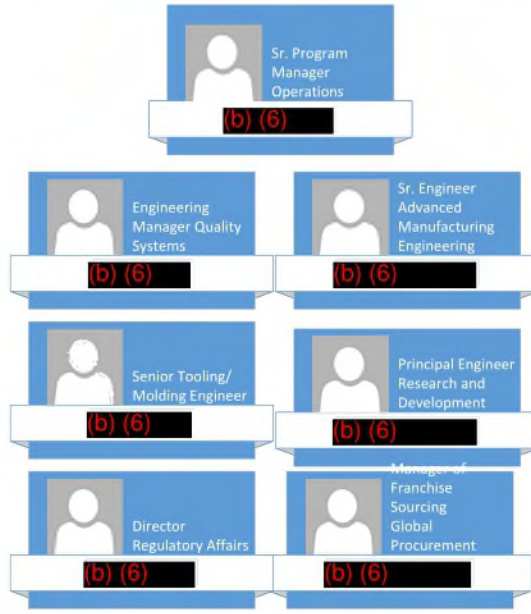
Ops	Site QE	Site Quality Engineering
	Site ME	Site Manufacturing Engineering
	AME	Operations: Advanced Manufacturing Engineering
	GLS	Operations: Global Sourcing
	LBL	Global Labeling
	MFE	Manufacturing Engineering
	SCN	Supply Chain Planning
	SQE	Supplier Quality Engineering
	MICROBIO	Microbiology
R&D	FUNCT ME	R&D Functional Engineering Mechanical Engineering
	PENG	Packaging Engineering
	PLE	Product Line Engineering
	TOX	Biocompatibility/Toxicology
GQR	QOM	Quality Operations - Microbiology
	DAS	Design Assurance
	Tech Comm	Technical Communications
	RAF	Regulatory Affairs
Misc.	FIN	Finance
	PM	Project/ Program Manager (Individual serving PM role - e.g., AME as the PM for a Sustaining project)
	GPM	Global Product Management



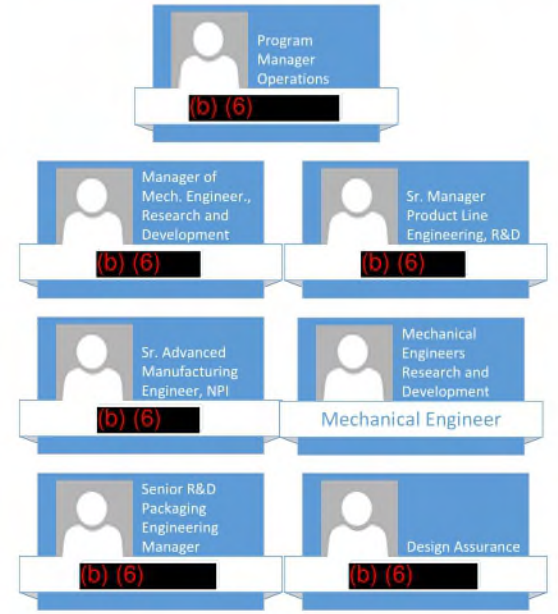
Core Team 1 (Phase I Execution)



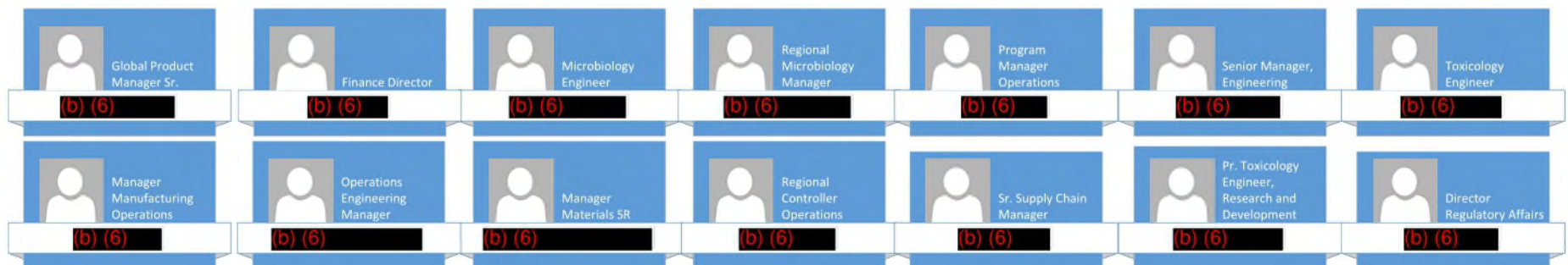
Core Team 2 (Phase II Execution)



Core Team 3 – SKU Expansion



Extended Core Team Support



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**Amendment to the
Non-Exclusive Distribution Agreement**

THIS AMENDMENT (the "Amendment") effective as of the last date written below (the "Amendment Effective Date"), is made to that certain Non-Exclusive Distribution Agreement with an Effective Date of (b) (4) subsequently amended in (b) (4) (the "Agreement"), by and between Smiths Medical ASD, Inc., a Delaware corporation, having an office at 6000 Nathan Lane North, Minneapolis, MN 55442 ("Smiths Medical"), and (b) (4) ("Distributor"). Unless specified otherwise within this Amendment, all capitalized terms used in this Amendment shall have the same meaning as they do in the Agreement.

Recitals

WHEREAS, pursuant to the terms of the Agreement, Smiths Medical sells Products to Distributor for resale within the Territory; and

WHEREAS, Smiths Medical has or will enter into an agreement with the U.S. Government pursuant to which the U.S. Government will provide certain funds to Smiths Medical to support Smiths Medical's purchase and implementation of a new Edge™ assembly line in its Keene, NH facility (the "New Line") to produce the following Smiths Medical product SKUs: (b) (4) (the "US Government Products");

WHEREAS, in exchange for its investment and the rights of citizens to request government action, the U.S. Government expects and requires that: (1) no third party will (b) (4) for the US Government Products produced by Smiths Medical using the New Line; and (2) that upon Presidential Declaration of a Public Health Emergency, the U.S. Government's orders for the US Government Products produced on the New Line will be prioritized over non-governmental orders;

WHEREAS, the parties desire to amend the Agreement to extend the Term for a period of three (3) years and guarantee that: (1) Distributor will not sell the US Government Products produced on the New Line to any third party (b) (4) US Government Products to the U.S. Government; and (2) that upon Presidential Declaration of a Public Health Emergency, Distributor shall prioritize the U.S. Government's orders for the US Government Products produced on the New Line over all non-governmental orders on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual promises, representations and covenants set forth herein, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. (b) (4)

2. Prices for US Government Products: During the Term of the Agreement, Distributor agrees that it shall not sell the US Government Products produced by Smiths Medical using the New Line to any third party at a (b) (4) US Government Products to the U.S. Government.

3. **Government Priority.** During the Term of the Agreement, Distributor agrees that upon Presidential Declaration of a Public Health Emergency, Distributor shall prioritize the U.S. Government's orders for the US Government Products produced on the New Line over all non-governmental orders for the US Government Products.

Smiths Medical shall duly prioritize orders Distributor places on behalf of the Government for US Government Products during a Presidential Declaration of a Public Health Emergency.

4. **Construction.** Notwithstanding that this Amendment has been prepared by Smiths Medical, Distributor and Smiths Medical confirm that this Amendment constitutes the understanding of the parties and is intended to be construed in a manner that is consistent with the subject matter and activities contemplated by, and the terms and conditions of, the Agreement. No rule of strict construction with respect to this Amendment shall be applied against either Smiths Medical or Distributor.

5. **Counterparts.** This Amendment and any subsequent amendment to the Agreement may be executed in several counterparts and by each party on a separate counterpart, each of which, when so executed and delivered shall be an original, but all of which together shall constitute but one and the same instrument. A fax signature or signature delivered as an imaged attachment to an e-mail message shall be deemed equivalent to an original ink signature. This Amendment (and any subsequent amendment) shall not become binding on any party until each party to the Agreement has transmitted to the other party or parties a counterpart executed by the transmitting party.

Other than the changes set forth in the preceding paragraphs, all other terms and conditions of the Agreement shall remain unchanged and in full force and effect.

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Amendment as of the dates set forth below.

Smiths Medical ASD, Inc.

(b) (6)

Dated: 10-Jul-2020

Marathon Medical Corporation

(b) (6)

Dated: 07-10-2020

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