

CONTRACT DATA REQUIREMENTS LIST
(2 Data Items)

Form Approved
OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 220 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.

A. CONTRACT LINE ITEM NO.	B. EXHIBIT A	C. CATEGORY: TDP _____ TM _____ OTHER <u>General/Admin Data</u>
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D. SYSTEM/ITEM Production of AS03 Adjuvant to support Exemption (b)(4) doses	E. CONTRACT/PR NO.	F. CONTRACTOR GlaxoSmithKline, LLC
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1. DATA ITEM NO. A001	2. TITLE OF DATA ITEM Quality Assessment Report	3. SUBTITLE Quality Report
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4. AUTHORITY (Data Acquisition Document No.) DI-QCIC-81187 (Tailored)	5. CONTRACT REFERENCE C.4.a	6. REQUIRING OFFICE BARDA
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7. DD 250 REQ No	9. DIST STATEMENT REQUIRED A	10. FREQUENCY Once	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION			
8. APP CODE NA		11. AS OF DATE NA	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES		
					Draft	Final	
						Reg	Repro

16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. & 13. The contractor shall submit the Quality Report within 30 days of award for Government review. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: (b) (6) * and the Contracting Officer** (KO), (b) (6)	15. TOTAL →	1	2	0
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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

1. DATA ITEM NO. A002	2. TITLE OF DATA ITEM Conference Minutes	3. SUBTITLE Monthly Teleconferences and Communication
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4. AUTHORITY (Data Acquisition Document No.) DI-ADMN-81250 (Tailored)	5. CONTRACT REFERENCE C.4.b	6. REQUIRING OFFICE BARDA
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7. DD 250 REQ No	9. DIST STATEMENT REQUIRED A	10. FR QUENCY Monthly	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION			
8. APP CODE NA		11. AS OF DATE NA	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES		
					Draft	Final	
						Reg	Repro

16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. & 13. 1). The contractor shall provide agendas and read-ahead material as required one day prior to the meetings and shall provide minutes of each meeting to the Government. 2). The contractor shall include key subcontractors as attendees at these teleconferences when applicable. 3). The contractor shall provide meeting minutes within three (3) business days after each formal scheduled meeting/teleconference conducted with the Government. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: (b) (6) * and the Contracting Officer** (KO), (b) (6)	15. TOTAL ▶	2	2	0
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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

G. PREPARED BY Exemption (b)(6)	H. DATE Exemption (b)(4)	I. APPROVED BY Exemption (b)(6)	J. DATE Exemption (b)(4)
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Reset

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A. CONTRACT LINE ITEM NO.	B. EXHIBIT A	C. CATEGORY: TDP _____ TM _____ OTHER <u>General/Admin Data</u>
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D. SYSTEM/ITEM Production of AS03 Adjuvant to support Exemption (b)(4) doses	E. CONTRACT/PR NO.	F. CONTRACTOR GlaxoSmithKline, LLC
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1. DATA ITEM NO. A003	2. TITLE OF DATA ITEM Conference Minutes	3. SUBTITLE Ad Hoc Meetings
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4. AUTHORITY (Data Acquisition Document No.) DI-ADMN-81250 (Tailored)	5. CONTRACT REFERENCE C.4.c	6. REQUIRING OFFICE BARDA
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7. DD 250 REQ No	9. DIST STATEMENT REQUIRED A	10. FREQUENCY As Required	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION		
8. APP CODE NA		11. AS OF DATE NA	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES	
					Draft	Final

16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . 9. Distribution Statement A: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. & 13. In addition to the monthly meetings, additional ad hoc meetings to address specific issues or to convey time-sensitive updates or scientific data related to the program will be held.. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: (b) (6) *, and the Contracting Officer** (KO), (b) (6))	15. TOTAL →	0	2	0
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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

1. DATA ITEM NO. A004	2. TITLE OF DATA ITEM Incident Report	3. SUBTITLE Incident Report
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4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-82071 (Tailored)	5. CONTRACT REFERENCE C.4.d	6. REQUIRING OFFICE BARDA
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7. DD 250 REQ No	9. DIST STATEMENT REQUIRED A	10. FREQUENCY As Required	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION		
8. APP CODE NA		11. AS OF DATE NA	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES	
					Draft	Final

16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . 9. Distribution Statement A: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. & 13. A written summary report shall be submitted within three (3) business days of an incident, to include what happened, what was the impact, if there are any available corrective actions and a time line for when the corrective actions would be in place. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: (b) (6) *, and the Contracting Officer** (KO), (b) (6))	15. TOTAL ▶	0	2	0
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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

G. PREPARED BY Exemption (b)(6)	H. DATE Exemption (b)(4)	I. APPROVED BY Exemption (b)(6)	J. DATE Exemption (b)(4)
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A. CONTRACT LINE ITEM NO.	B. EXHIBIT A	C. CATEGORY: TDP _____ TM _____ OTHER <u>General/Admin Data</u>
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D. SYSTEM/ITEM Production of AS03 Adjuvant to support Exemption (b)(4) doses	E. CONTRACT/PR NO.	F. CONTRACTOR GlaxoSmithKline, LLC
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1. DATA ITEM NO. A005	2. TITLE OF DATA ITEM Contract Summary Report	3. SUBTITLE Draft and Final Reports
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4. AUTHORITY (Data Acquisition Document No.) DI-ADMN-80447A	5. CONTRACT REFERENCE C.4.e	6. REQUIRING OFFICE BARDA
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7. DD 250 REQ No	9. DIST STATEMENT REQUIRED C	10. FREQUENCY Twice	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION		
8. APP CODE A		11. AS OF DATE NA	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES	
					Draft	Final
					Reg	Repro

16. REMARKS 4 The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ 9 Distribution Statement A: Distribution authorized to U S Government agencies and their Contractors (Administrative or Operational Use) Determination made July 18, 2020 Distribution guidance is included in DoD Instruction 5230 24 12 & 13 Due 30 calendar days before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP The Progress Report shall contain manufacturing process description including: • batch number • date and location of manufacture (including building, room, line number) • shelf life • description of process/testing • final production volume • complete list of analytical tests performed and results • Certificate(s) of Analysis • Certificate(s) of Current Good Manufacturing Practices (cGMP) Conformity • Any deviations • Final status, e g , released, etc 14 Submit as an electronic file in Microsoft Office (i e Word, Excel, Power Point) via email to the BARDA representative: (b) (6) *, and the Contracting Officer** (KO), Trishā (b) (6)	15. TOTAL →	1	2	0
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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
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4. AUTHORITY (Data Acquisition Document No.)	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
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7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION	14. DISTRIBUTION		
8. APP CODE		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION	a. ADDRESSEE	b. COPIES	
					Draft	Final
					Reg	Repro

16. REMARKS NOT USED	15. TOTAL ▶	1	2	0
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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

G. PREPARED BY Exemption (b)(6)	H. DATE Exemption (b)(4)	I. APPROVED BY Exemption (b)(6)	J. DATE Exemption (b)(4)
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A. CONTRACT LINE ITEM NO.	B. EXHIBIT A	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM Production of AS03 Adjuvant to support Exemption (b)(4) doses	E. CONTRACT/PR NO.	F. CONTRACTOR GlaxoSmithKline, LLC
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1. DATA ITEM NO. A006	2. TITLE OF DATA ITEM Internal Contractor Technical Data	3. SUBTITLE Product Development Source Material and Manufacturing Reports and Projections
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4. AUTHORITY (Data Acquisition Document No.) DI-SESS-81309	5. CONTRACT REFERENCE	6. REQUIRING OFFICE BARDA
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7. DD 250 REQ No	9. DIST STATEMENT REQUIRED C	10. FREQUENCY Monthly	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION		
8. APP CODE A		11. AS OF DATE NA	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES	
					Draft	Final

16. REMARKS 4 The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ 9 Distribution Statement C: Distribution authorized to U S Government agencies and their Contractors (Administrative or Operational Use) Determination made July 18, 2020 Distribution guidance is included in DoD Instruction 5230 24 12 & 13 1) The contractor will submit Product Development Source Material Report within month of contract award, within 30 days of substantive changes are made to sources and/or materials, or on the 6th month contract anniversary 2) The contractor will update the Dose Tracking Template weekly during manufacturing campaigns and daily during response operations (where a Public Health Emergency has been declared) and COVID-19 response, with the first deliverable submission within 15 days of award/modification Updates to be provided weekly in advance of commercial-scale manufacturing and daily once material for use in response operations begins manufacture 3) The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission If corrective action is recommended, Contractor must address all concerns raised by BARDA in writing The Product Development and Source Material report to be submitted via spreadsheet; Dose Tracking can be completed via spreadsheet or other format (e.g XML or JSON) as agreed to by USG and company 14 Submit as an electronic file in Microsoft Office (i.e Word, Excel, Power Point) via email to the BARDA representative: (b) (6) *, and the Contracting Officer** (KO), (b) (6)	15. TOTAL →	0	2	0
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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

1. DATA ITEM NO. A007	2. TITLE OF DATA ITEM Contract Summary Report	3. SUBTITLE Contractor Location
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4. AUTHORITY (Data Acquisition Document No.) DI-ADMN-80447A	5. CONTRACT REFERENCE	6. REQUIRING OFFICE BARDA
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7. DD 250 REQ NO	9. DIST STATEMENT REQUIRED C	10. FREQUENCY Once	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION		
8. APP CODE NA		11. AS OF DATE NA	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES	
					Draft	Final

16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. & 13. The contractor will submit Work Locations Report within 5 business days of contract award, within 30 business days after a substantive location or capabilities change, and within 2 business days of a substantive change if the work performed supports medical countermeasures development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: (b) (6) *, and the Contracting Officer** (KO), (b) (6)	15. TOTAL ▶	0	2	0
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17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

G. PREPARED BY Exemption (b)(6)	H. DATE Exemption (b)(4)	I. APPROVED BY Exemption (b)(6)	J. DATE Exemption (b)(4)
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Reset