(Updated 20250617)

CONTRACT DATA REQUIREMENTS LIST

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY:
0001-0003 (all)	A001	☐ TDP ☐ TM ☒ OTHER General Data

D. SYSTEM / ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
Single Use Analgesic Product Development	TBD	TBD

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
A001	Single Use Analgesic Product	N/A

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
DI-TCSP-82040	See Statement of Objectives (SOO)	OPMED

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
See blk 16 below	See blk 16 below	See SOO Section 4	See SOO
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See SOO	See SOO

17. PRICE GROUP
III

18. ESTIMATED TOTAL PRICE
Not Separately Priced (NSP)

16. REMARKS

Blk 4. Data Item Deliverable (DID) No. DI-TCSP-82040 can be obtained from https://quicksearch.dla.mil/qsSearch.aspx, type in "DI-TCSP-82040" under "Document ID" and click "search."

Blk 7. Acceptance and Inspection of described technical data and deliverables will be performed by Portfolio Acquisition Executive Medical Products (PAEMP) and comments on the Data Deliverables will be provided within ten (10) days. PAEMP will have five (5) days to respond to any questions. All final Data Deliverables with incorporated changes shall be submitted back to OPMED five (5) days after receipt of government comments.

Blk 9 - The technical data purchased under this Prototype Other Transaction Agreement (pOTA) will not be distributed outside the Government for other than government purposes unless, pursuant to the terms of this Prototype Other Transaction Agreement (pOTA). The Government exercises its unlimited rights therein.

Blks 11, 12, and 13 - The Performer shall submit all Data Deliverables for the development of the single use analgesic product in accordance with the SOO (or IMS). This includes:
1. Quality Management Plan (deliverable 11 of the SOO). See DI-TCSP-82040 Section 2.f.(2)
2. Regulatory Strategy (deliverable 13 of the SOO). See DI-TCSP-82040 Section 2.a.(1)
3. Regulatory Correspondence, Documentation, and FDA Submissions (deliverable 14 of the SOO). See DI-TCSP-82040 Section 2.b.(2-4)
4. Written FDA Responses and Meeting Minutes (deliverable 15 of the SOO). See DI-TCSP-82040 Section 2.b.(1)
5. Clinical Documentation / Report / Submission (deliverable 17 of the SOO). See DI-TCSP-82040 Section 2.d.
6. Interim and Final Clinical / Non-Clinical / Human Factors Study Execution and Report (deliverable 19 of the SOO). See DI-TCSP-82040 Section 2.c. and Section 2.d.
7. Stability Test Plan (deliverable 20 of the SOO). See DI-TCSP-82040 Section 2.e.(16)
8. Stability Studies Reports (deliverable 21 of the SOO). See DI-TCSP-82040 Section 2.e.(16)
9. Manufacturing Process Validation Report (deliverable 22 of the SOO). See DI-TCSP-82040 Section 2.a.(5)
10. Manufacturing Documentation / Reports / Submission (deliverable 25 of the SOO). See DI- TCSP-82040 Section 2.e.
11. Clinical / Non-Clinical / Human Factors Study Protocols (deliverable 26 of the SOO). See DI-TCSP-82040 Section 2.c.(1-2) and Section 2.d.(1)

Blk 14 & Blk I5. Submit via e-mail in pdf format to:
a. Government Agreement Officer Representative (AOR)

14. DISTRIBUTION			
a. ADDRESSEE	b. COPIES		
	Draft	Final	
		Reg	Repro
See Block 16			
15.TOTAL →	0	0	0

G. PREPARED BY	H. SIGNATURE	I. APPROVED B	J. SIGNATURE
[redacted]		[redacted]	

INSTRUCTIONS FOR COMPLETING DD FORM 1423

(See DoDM 5010.12 for detailed instructions.)

FOR GOVERNMENT PERSONNEL

Item A. Self-explanatory.

Item B. Self-explanatory.

Item C. Mark (X) appropriate category: TDP - Technical Data Package; TM - Technical Manual; Other - other category of data, such as "Provisioning," "Configuration Management," etc.

Item D. Enter name of system/item being acquired that data will support (e.g., Mission Design Series (MDS) designator).

Item E. Self-explanatory (to be filled in after contract award).

Item F. Self-explanatory (to be filled in after contract award).

Item G. Name of preparer of CDRL.

Item H. Date CDRL was prepared and signature of preparer of CDRL.

Item I. Name of CDRL approval authority.

Item J. Date CDRL was approved and signature of CDRL approval authority.

Item 1. See DFARS Subpart 204.71 for proper numbering. To add or delete additional data items, point and click the plus or minus sign to the right of Block J.

Item 2. Enter title as it appears on data acquisition document cited in Item 4.

Item 3. Enter subtitle of data item for further definition of data item (optional entry).

Item 4. Identify only one Data Acquisition Document No. If a single work task generates more than one deliverable data product, prepare a separate data item for each deliverable data product.

Item 5. Enter reference to tasking in contract that generates requirement for the data item (e.g., Statement of Work/Performance Work Statement paragraph number).

Item 6. Enter technical office responsible for ensuring adequacy of the data item.

Item 7. Specify requirement for inspection/acceptance of the data item by the Government.

Item 8. Specify requirement for approval of a draft before preparation of the final data item.

Item 9. For technical data and computer software, specify the contractor's requirement to mark the appropriate distribution statement on the technical data or computer software (ref. DoDI 5230.24).

Item 10. Specify number of times data items are to be delivered.

Item 11. Specify as-of date of data item, when applicable.

Item 12. Specify when first submittal is required.

Item 13. Specify when subsequent submittals are required, when applicable.

Item 14. Enter addressees and number of draft/final copies to be delivered to each addressee. Explain reproducible copies in Item 16.

Item 15. Enter total number of draft/final copies to be delivered.

Item 16. Use for additional/clarifying information for Items 1 through 15. Examples are: Tailoring of documents cited in Item 4; Clarification of submittal dates in Items 12 and 13; Explanation of reproducible copies in Item 14; Desired medium for delivery of the data item.

Identify for which data item additional remarks are provided. When tailoring the Data Acquisition Document invoked in Item 4, identify which portions of that Document are being tailored.

Identify any referenced attachments to the form. Attachments can be added using the button at the bottom of page 1.

FOR THE CONTRACTOR

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

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

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

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

Estimated Price - Costs to be included under Group II are those incurred over and above the cost of the essential data item without conforming to Government requirements, and the administrative and other expenses related to reproducing and delivering such data item to the Government.

c. Group III. Definition - Data which the contractor must develop for his internal use in performance of the primary contracted effort and does not require any substantial change to conform to Government requirements with regard to depth of content, format, frequency of submittal, preparation, control, and quality of the data item.

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

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

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

Item 18. For each data item, enter an amount equal to that portion of the total price which is estimated to be attributable to the production or development for the Government of that item of data.

These estimated data prices shall be developed only from those costs which will be incurred as a direct result of the requirement to supply the data, over and above those costs which would otherwise be incurred in performance of the contract if no data were required. The estimated data prices shall not include any amount for rights in data. The Government's rights to use the data shall be governed by the pertinent provisions of the contract.