Attachment A

Statement of Objectives
for
Analgesic Product for Battlefield Use

Date: 04 MAR 2026

Revised date:

Project Title: Analgesic Product for Battlefield Use

Requiring Activity/Agency Name: Defense Health Agency, Portfolio Acquisition Executive Medical Products (PAE MP), Warfighter Protection and Acute Care Project Management Office (WPAC PMO), Fort Detrick, MD

Program Name: Battlefield Pain Management

1. PURPOSE/OBJECTIVE

The purpose of this prototype development is to achieve the U.S. Food and Drug Administration (FDA) approval for a single use analgesic product with an indication for moderate to severe acute pain management. An Emergency Use Authorization (EUA) may be used as a strategy for early delivery to the Joint Warfighter.

The prototype development efforts must be compliant with 21 Code of Federal Regulations (CFR) Part 58 and Part 11 and follow FDA's Guidance for Industry; Essential Drug Delivery Outputs for Devices Intended to Deliver Drugs and Biological Products Guidance for Industry; and Guidance for Industry and FDA Staff: Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products. As applicable, data submitted to the FDA must be generated, compiled, and packaged in compliance with FDA Investigational New Drug (IND) submission requirements (Clinical Data Interchange Standards Consortium (CDISC) Standard for Exchange of Nonclinical Data (SEND) format).

The drug is primarily intended to be used during Tactical Combat Casualty Care (TCCC) at or near the point of injury in austere environments. The single use analgesic product will be part of the battlefield pain management response during Prolonged Casualty Care (PCC) and used during casualty evacuation (CASEVAC)/medical evacuation (MEDEVAC) and at all Roles of Care (ROC). The goal of developing a single use analgesic product is to have a rapid, single dose/single use product with a specific analgesic indication for moderate to severe pain as part of the Battlefield Pain Management (BPM) Family of Systems (FoS). The BPM FoS will provide for comprehensive closure of the Joint Force's pain management gaps.

Work under this Statement of Objectives (SOO) is intended to result in no more than two awards for the prototyping of an FDA approved single use analgesic product with an indication for moderate to severe acute pain management.

The long-term goal is to have the single use analgesic product fielded and eventually included in standard issue sets/kits/outfits for the Joint Force, which may be part of a follow-on requirement.

2. BACKGROUND

The BPM program addresses the need for austere, pre-hospital TCCC and Large Scale Combat Operations (LSCO) compatible analgesics for moderate to severe acute pain. BPM is using a FoS approach to address this capability gap. This requirement is to fund FDA approval of a single use analgesic product, which will act as backfill for the loss of both DSUVIA (sublingual sufentanyl) and Oral Transmucosal Fentanyl Citrate (OTFC). The product will provide a rapid and easy to use, single dose analgesic.

3. SCOPE OF EFFORT

Work under this SOO is intended to result in at least one award for the prototyping of an FDA approved analgesic product with an indication for moderate to severe acute pain management. Submission and use of the product under an EUA may be a strategy for early delivery pending the publishing of an appropriate Emergency Declaration.

The product will be carried by medics, and potentially individual Warfighters, in the field and shall maintain effectiveness in rugged, austere, pre-hospital scenarios. The studies and product development must be compliant with 21 CFR Part 58 and Part 11 and follow FDA's Guidance for Industry, as applicable. The effort may include both non-clinical and clinical studies, human factors testing, data analysis, data packaging and submission as well as any tasks and studies required to satisfy FDA requirements and allow for product licensure.

4. OBJECTIVES

The Performer shall complete the objectives which lead to the FDA approval of the single use analgesic product with an indication for acute moderate to severe acute pain.

Please refer to Section 9 "Constraints" for minimum/desirable drug characteristics and performance.

Meeting the objectives broadly includes completing device and drug development and testing requirements. This will include Chemistry Manufacturing Controls (CMC) requirements to meet FDA drug and device manufacturing requirements (Objective 1) as well as stability studies to determine the shelf life of the product (Objective 1). Meeting the objectives will also include Non-clinical enabling studies for the product (Objective 2); followed by a Phase 2/3 clinical trial in patients as well as human factor studies and a possible EUA submission (Objective 3).

The Performer shall include all needed tasks in the statement of work (SOW) and milestones.

Objective 1: Complete CMC requirements to meet FDA drug and device, as necessary, manufacturing requirements and stability studies to determine the shelf life of the product.

The Performer shall coordinate a kick-off meeting with Government and produce meeting minutes **(Deliverable 1)**. Participate in monthly status meetings **(Deliverable 2)** monthly CMC Team meetings **(Deliverable 3)** and monthly Regulatory Meetings **(Deliverable 4)**. Complete monthly report **(Deliverable 5)**, Project Management Plan (PMP) **(Deliverable 6)**, Subcontractor Management Plan **(Deliverable 7)**, Integrated Master Schedule **(Deliverable 8)**, Work Breakdown Structure (WBS) **(Deliverable 9)**, Spend Plan **(Deliverable 10)**, Quality Manufacturing Plan (QMP) **(Deliverable 11)**, Chemistry Manufacturing Controls (CMC) Plan **(Deliverable 12)**, Regulatory strategy **(Deliverable 13)**, and Stability Test Plan **(Deliverable 20)**

Manufacturing process validation report **(Deliverable 22)**, manufacturing documentation/reports/submission **(Deliverable 25)**, Regulatory correspondence, documentation, and FDA submissions **(Deliverable 14)** and clinical documentation/reports/submissions **(Deliverable 17)** are to be submitted to the Agreements Officer's Representative (AOR) as are all written FDA responses and meeting minutes **(Deliverable 15)**. Stability Studies Reports **(Deliverable 21)** shall also be provided. Commercial manufacturing sales must be reached **(Deliverable 23)**. The final product is an FDA approved single use analgesic product indicated for moderate to severe acute pain, demonstrated by a notice of FDA approval **(Deliverable 24)**.

Objective 2: Complete non-clinical enabling study (must be completed <u>prior to</u> starting Objective 3).

The Performer shall ensure that non-clinical enabling studies are completed and accepted by the FDA. The non-clinical studies shall be used to enable clinical studies in Objective 3. The Performer shall submit a non-clinical study strategy **(Deliverable 16)**, documentation/reports/submissions **(Deliverable 17)** are to be submitted to the Agreements Officer's Representative (AOR) as well as all written FDA responses and meeting minutes **(Deliverable 15)**, Prior to the start of any non-clinical studies involving animals, the Performer shall obtain approval of the protocols **(Deliverable 26)** from an Institutional Animal Care & Use Committee (IACUC) **(Deliverable 18)**. Prior to the start of any clinical studies involving humans, the Performer shall obtain approval of the protocols **(Deliverable 26)** from the Office of Research and Regulatory Compliance (ORRC) **(Deliverable 18)**. Interim and final clinical, non-clinical, and human factor Study Reports **(Deliverable 19)** shall be submitted to the AOR.

Objective 3: Complete Phase 1/2/3 clinical trial and human factor studies.

The Performer shall complete the necessary clinical studies and human factors studies required for the FDA approval of the single use analgesic product. The specific studies required will be made in consultation with the FDA after the FDA reviews the IND submission. The Performer shall submit a clinical and human factors study strategy **(Deliverable 16)**, documentation/reports/submissions **(Deliverable 17)** are to be submitted to the AOR as well as all written FDA responses and meeting minutes **(Deliverable 15)**, Prior to the start of any clinical studies or human factor studies involving humans, the Performer shall obtain approval of the protocols **(Deliverable 26)** from the Office of Research and Regulatory Compliance (ORRC) **(Deliverable 18)**. Interim and Final clinical and non-clinical Study Reports **(Deliverable 19)** shall be submitted to the AOR.

FDA requirements for a possible EUA will be included under the relevant Deliverables above.

5. PERIOD PERFORMANCE

The estimated period of performance (PoP) for the entire effort is 8 years.

The estimated PoP for Objective 1 is 3 years.

The estimated PoP for the non-clinical studies in Objective 2 is 2 years.

The estimated PoP for Objective 3 is 3 years (must be executed after the completion of Objective 2 – non-clinical enabling studies).

6. LOCATION

The place of performance may involve Continental United States (CONUS) and Outside the Continental United States (OCONUS) locations. The Performer shall identify potential sub-contracting partners and geographic locations (i.e., in the U.S. and/or outside of the U.S.).

Development shall be conducted at the Performer's location.

The Performer shall identify potential sub-contracting partners and geographic locations (i.e., in the U.S. and/or outside of the U.S.) in the technical proposal.

7. TRAVEL

Travel of 1 to 3 Performer personnel (ex: project manager and technical developers) may be required to support technical demonstrations, training at DoW facilities, and Military exercises in CONUS, Alaska, and Hawaii. Travel to other locations may be required for prototype demonstrations and meetings, to professional and DoW conferences, and for oversight on non-clinical and clinical studies.

8. GOVERNMENT FURNISHED PROPERTY

No government-furnished property will be provided during performance.

9. CONSTRAINTS

a. Animal Care and Use Review Office (ACURO) approval.

Research under this requirement involving the use of animals **SHALL NOT** begin until the Defense Health Agency (DHA) Component Animal Oversight Office Animal Care and Use Review Office (ACURO) provides authorization that the research may proceed. Written approval to begin research shall be issued from the USAMRDC ACURO, under separate notification to the recipient. Written approval from the USAMRDC ACURO is also required for any sub-awardee that shall use funds from this award to conduct research involving animals. See

Agreement Terms & Conditions, Article 14 General Provisions for submission requirements. The DoW funding for animal studies involving companion animals (cats and dogs), is dependent on the Institutional Animal Care and Use Committee (IACUC) determination that the study meets the U.S. Department of Agriculture (USDA) criteria for pain Category C or below.

b. Office of Research and Regulatory Compliance (ORRC).

Research under this award involving the use of human subjects, to include the use of human anatomical substances or identifiable private information, **SHALL NOT** begin until ORRC provides authorization that the research may proceed. Written approval to begin research shall be issued from the ORRC, under separate notification to the recipient. Written approval from ORRC is also required for any sub-awardee that will be using funds from this award to conduct research involving human subjects or human anatomical substances. See Agreement Terms & Conditions, Article 14 General Provisions for submission requirements.

Per FDA guidelines, the Performer shall ensure that Good Laboratory Practice (GLP) recommendations are followed for any animal studies. The studies and product development must be compliant with 21 CFR Part 58 and Part 11 and follow FDA's various guides for industry, as applicable.

Desirable prototype characteristics and performance: To provide reliable and effective performance, the DoW requires a drug that can meet the Final Drug Characteristics (Minimum Requirement) are:

Evaluation will also be based on the response to the following product characteristics

(1) The product shall have a form that is usable for austere, pre-hospital conditions.

(2) The product shall be a single dose product with an intramuscular (IM), intranasal (IN), or oral (PO) route of administration.

(3) The single dose delivered shall be sufficient to induce analgesia for acute moderate to severe pain.

(4) The product shall have a shelf life of 2-3 years at controlled room temperature

(5) The product shall be operable in cold, cool, warm, and excessive heat temperatures, as defined in the United States Pharmacopeia (USP) <659> Packing and Storage Requirements.

(6) The performer shall have large scale manufacturing capability and ability to surge production.

(7) The product shall not require refrigeration at any point after procurement and can withstand excursions to temperatures between 45ºC and -25ºC.

(8) The product shall be indicated for moderate to severe or severe pain upon FDA approval. The analgesic indication shall not be added to the product after FDA approval for another indication (e.g. anesthesia induction).

(9) The performer shall meet statutory and regulatory requirements to manufacture, store, and distribute controlled drug substances.

(10) The product may be a combination drug.

(11) The product may use an applicator device (e.g. autoinjector or nasal spray) that may or may not have a predicate device.

(12) The product may meet Drug Enforcement Administration (DEA) uncontrolled classification criteria.

(13) The product shall be classified as DEA schedule II or higher.

(14) The product shall be rapid and easy to administer.

(15) The product shall have small weight and cube for easy individual carry of multiple doses.

(16) The product shall have minimal physiological risks, especially to pulmonary arrest, cardiovascular stability, loss of blood pressure, and blood clotting.: ≤ 20% decrease in baseline blood pressure and heart rate; ≤ 20% decrease in the blood's ability to clot; minor change in airway, not requiring ventilation.

(17) The product should have minimal impact on mental status.

(18) The product shall have a rapid onset (≤ 10 minutes) and a long duration of analgesic activity (≥ 30 minutes).

(19) Product and all source materials shall be manufactured and purchased in accordance with Trade Act Agreement (TAA) compliance and certification provided.

(20) The product shall not require reconstitution.

10.0 DELIVERABLES

Method of Delivery: Electronic copies shall be delivered using Microsoft Office suite of tools (for example, MS Word, MS Excel, MS PowerPoint, MS Project, or MS Access format), unless otherwise specified by the PAE MP AOR. Electronic submission shall be made via email, unless otherwise agreed to by the PAE MP AOR. The Performer shall make use of commercial best practices in the packing and shipment of packages.

Acceptance and Inspection of described technical data and deliverables will be performed by PAE MP and comments on the Data Deliverables will be provided back to the Performer within

10 days. PAE MP will have 5 days to respond to any questions raised by the Performer. All final Data Deliverables with incorporated changes shall be submitted back to PAE MP 5 days after receipt of government comments.

Deliverable	SOO Reference	Distribute To	Format	Initial Delivery	Subsequent Delivery
1. Joint Government/ Performer Kick-off Meeting & Meeting Minutes	Objective 1	Agreements Officer (AO), Agreements Specialist (AS) and AOR	Virtual	Due NLT 30 business days after award. Draft minutes NLT 7 business days post-meeting	N/A
2. Monthly Meetings & Agenda	Objectives 1-3	AOR	Virtual	Due NLT the 15th of each month, starting at the month after the Kick-Off Meeting	Due NLT the 15th of each calendar month. Meeting agenda provided three (3) business days **prior to** meeting.
3. Monthly Chemistry Manufacturing Controls (CMC) Meeting & Agenda	Objectives 1	AOR	Virtual	Due 60 days after award	Due NLT 15 days after the end of each calendar month. Meeting agenda provided three (3) business days **prior to** meeting.
4. Monthly Regulatory Meeting & Agenda	Objectives 1-3	AOR	Virtual	Within 60 days of award	Due NLT 15 days after the end of each calendar month. Meeting Agenda provided three (3) business days **prior to** meeting.
5. Monthly Status Report	Objectives 1-3	AOR	Electronic format: mutual agreement between Gov't & Performer	Due NLT 7 business days after the first calendar month	Due NLT 7 days after the end of each calendar month.

Deliverable	SOO Reference	Distribute To	Format	Initial Delivery	Subsequent Delivery
6. Project Management Plan (PMP)	Objective 1	AOR	Electronic format: mutual agreement between Gov't & Performer	Due at the time of proposal submission	Due every six (6) months **or** thirty (30) days after government request
7. Subcontractor Management Plan	Objective 1	AOR	Electronic format: mutual agreement between Gov't & Performer	Due at the time of proposal submission	Updated and provided within thirty (30) days of Government request and/or each time a subcontractor is changed.
8. Integrated Master Schedule (IMS)	Objective 1	AOR	Electronic format: mutual agreement between Gov't & Performer	Due at the time of proposal submission	NLT thirty (30) calendar days after contract award, within thirty (30) days of Government request and/or every six (6) months.
9. Work Breakdown Structure (WBS)	Objective 1	AOR	Electronic format: mutual agreement between Gov't & Performer	Due at the time of proposal submission	Due every six (6) months **or** thirty (30) days after government request
10. Spend Plan	Objective 1	AOR	Electronic format: mutual agreement between Gov't & Performer	Due within 30 days of award.	Due with the Monthly Status report
11. Quality Management Plan (QMP) (reference CDRL A001, DID DI-TCSP-82040)	Objective 1	AOR	Electronic format: mutual agreement between Gov't & Performer	Due within 30 days of contract award.	Due every six (6) months **or** thirty (30) days after government request

Deliverable	SOO Reference	Distribute To	Format	Initial Delivery	Subsequent Delivery
12. Chemistry, Manufacturing, and Controls (CMC) Plan	Objective 1	AOR	Electronic documents	Due within 30 days of contract award.	Due every six (6) months **or** thirty (30) days after government request
13. Regulatory Strategy (reference CDRL A001, DID DI-TCSP-82040)	Objectives 1-3	AOR	Electronic document	Due at the time of proposal submission	Due every six (6) months **or** thirty (30) days after government request
14. Regulatory correspondence, documentation, and FDA submissions (reference CDRL A001, DID DI-TCSP-82040)	Objectives 1-3	AOR	Electronic documents	No later than 5 business days prior to submission, dependent on document quantity and within two (2) business days of interaction.	Within five (5) business days of submission and (2) business days of interaction.
15. Written FDA responses and meeting minutes (reference CDRL A001, DID DI-TCSP-82040)	Objectives 1-3	AOR	Electronic documents	Due NLT 3 days after receipt from the FDA.	Due NLT 3 days after receipt from the FDA.
16. Clinical/ non-clinical / human factors Strategy	Objectives 1-3	AOR	Electronic document	Due at the time of proposal submission	Updated and provided within thirty (30) days of Government request and/or every six (6) months.

Deliverable	SOO Reference	Distribute To	Format	Initial Delivery	Subsequent Delivery
17. Clinical documentation / report / submission (reference CDRL A001, DID DI-TCSP-82040)	Objectives 1-3	AOR	Electronic document	Due NLT 5 business days prior to submission to the FDA	Due NLT 5 business days prior to submission to the FDA
18. DHA's Office of Research and Regulatory Oversight (ORRC) and IACUC approval	Objectives 2-3	AOR	Electronic document	Prior to study initiation	N/A
19. Interim and Final Clinical/ Non-clinical/ Human Factors Study Execution & Report (reference CDRL A001, DID DI-TCSP-82040)	Objectives 1-3	AOR	Electronic documents	Interim report due 5 days after completion and final report due within 3 months of project completion	N/A
20. Stability Test Plan (reference CDRL A001, DID DI-TCSP-82040)	Objective 1	AOR	Electronic document	Due within 30 days after project start	As updates occur
21. Stability studies reports (reference CDRL A001, DID DI-TCSP-82040)	Objective 1	AOR	Electronic documents	Interim report due 5 days after completion and final report due within 3 months of project completion	N/A

Deliverable	SOO Reference	Distribute To	Format	Initial Delivery	Subsequent Delivery
22. Manufacturing Process Validation Report (reference CDRL A001, DID DI-TCSP-82040)	Objective 1	AOR	Electronic document	Before end of clinical study	N/A
23. Commercial manufacturing sales plan	Objective 1	AOR	Electronic document	Due at the time of proposal submission	N/A
24. FDA approval	Objectives 1-3	AOR	Electronic document	Due NLT 1 business day after notification from the FDA	N/A
25. Manufacturing documentation / reports / submission (reference CDRL A001, DID DI-TCSP-82040)	Objective 1	AOR	Electronic document	Due NLT 5 business days prior to submission to the FDA	Due NLT 5 business days prior to submission to the FDA
26. Clinical/ non-clinical / human factors Study Protocols (reference CDRL A001, DID DI-TCSP-82040)	Objectives 1-3	AOR	Electronic documents	Within five (5) business days of Government's request or at the time of Institutional Review Board (IRB)M/IACUC submission.	Within five (5) business days of IRB approval, update/amendment, Study Report completion, Communication or within five (5) business days of Government's request; whichever occurs first.

11.0 ABBREVIATIONS

Attachment A

Abbreviation	Definition
ACURO	Animal Care and Use Review Office
AO	Agreements Officer
AOR	Agreements Officer's Representative
AS	Agreements Specialist
BPM	Battlefield Pain Management
°C	Degrees Celsius
CASEVAC	Casualty Evacuation
CDRL	Contract Data Requirements List
CDISC	Clinical Data Interchange Standards Consortium
CFR	Code of Federal Regulations
CMC	Chemistry Manufacturing Controls
CONUS	Continental United States
DID	Data Item Descriptions
DoD	Department of Defense
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
FoS	Family of Systems
GLP	Good Laboratory Practice
IACUC	Institutional Animal Care and Use Committee
IND	Investigational New Drug
IMS	Integrated Master Schedule
IRB	Institutional Review Board
LSCO	Large Scale Combat Operations
MEDEVAC	Medical Evacuation
MIL	Military
MS	Microsoft
MTA	Middle Tier of Acquisition
NLT	No Later Than
OCONUS	Outside Continental United States
OHRO	Office of Human Research Oversight
ORRC	Office of Research and Regulatory Compliance
PAE MP	Portfolio Acquisition Executive Medical Products
OTFC	Oral Transmucosal Fentanyl Citrate
PEO	Program Executive Office
PCC	Prolonged Casualty Care
PK	Pharmacokinetic
PMO	Project Management Office
PoP	Period of Performance
PMP	Project Management Plan
QMP	Quality Management Plan
ROC	Role of Care

Abbreviation	Definition
SEND	Standard for Exchange of Nonclinical Data
SOO	Statement of Objectives
SOW	Statement of Work
STD	Standard
TAA	Trade Act Agreement
TCCC	Tactical Combat Casualty Care
TBD	To be Determined
TRL	Technology Readiness Level
U.S.	United States
USAMRDC	Unites States Army Medical Research and Development Command
WBS	Work Breakdown Structure
WPAC	Warfighter Protection and Acute Care

(end of Statement of Objectives)