QUESTION	RESPONSE
17. iv. "Technical Readiness Level": The technology proposed must meet TRL 4 or above. Question: There does not appear to be a TRL applicable to the services being requested within the SOO for the CADENCC program. Please confirm whether it is acceptable to note "Not Applicable" for this requirement.	While not needed at this time, please confirm capability to meet TRL 4.
17. X. "Budget/Cost" Question: Does CPE have a specific scope of work and period of performance in which the offeror can base a budget? As currently written, the SOO does not provide sufficient detail to develop a budget or ROM for potential service support under the RPP. Please confirm whether it is acceptable to note "Not Applicable" for this requirement.	We ask for the offeror to provide a menu of services. The period of performance is Q1FY2027 to Q1FY2031. Consider the following assumptions: • Phase 1 study will enroll 40 participants • Phase 2 study will enroll 150 participants • Geographic scope is mainly the continental United States, but could potentially include global clinical sites should the need arise • Studies will be conducted at clinical sites and Military Treatment Facilities (MTFs) • Studies will be FDA regulated • Studies may require laboratory specimen collection and processing
17.xii Past Performance: Documented satisfactory performance record. Question: Does CPE have a specific format they would like past performance information included? Or, will CPE be reviewing the offerors CPARs? If Past Performance information is to be provided, can these be included as an Appendix that would not count against the 10 page count?	Offeror can provide past performance in any format. CPARs may be reviewed as applicable. May be included in the Appendix and will not count against the 10 page limit.
SAM Notice: "ROM" Question: The SAM notice notes a ROM shall be submitted. Does CPE have a specific scope of work and period of performance in which the offeror can use to develop a ROM? As currently written, the SOO does not provide sufficient detail to develop a budget or ROM for potential service support under the RPP.	Please review the assumptions provided under "Budget/Cost".
SAM Notice: Work Breakdown Structure: Question: The SAM notice notes a WBS shall be submitted. Can CPE confirm what type/level of information detail they would like included in the WBS?	WBS Level 4
Page Count (10 Pages) Question: Please confirm a Table of Contents will not count against the 10 page limit.	Will not count against the 10 page limit.

Request for Project Proposal. Does the Government envision a single award or multiple awards under this effort?	There will be a single award under this effort.
Request for Project Proposal. Should option efforts be separately priced?	Please price option efforts separately.
Request for Project Proposal. What is the anticipated Period of Performance (base and option periods, if applicable)?	There is one base year and four option years with a period of performance of Q1FY2027 to Q1FY2031
Request for Project Proposal, Page 4, Paragraph 16. Is a Rough Order of Magnitude Cost Estimate (ROM) and Work Breakdown Structure (WBS) required as part of the preproposal submission? The RPP references both ROM and WBS in Section 16 but does not explicitly require them.	ROM and WBS required.
Request for Project Proposal, Page 4, Paragraph 17.iv. The RPP includes this requirement: "Technology Readiness Level (TRL): The technology proposed must meet TRL 4 or above. See the attached for a full description of TRLs (QTRLS).", Please confirm whether this contract involves the development of a specific product or technology.	This contract involves the development of a clinical trial capability as a product. While not needed at this time, please confirm capability to meet TRL 4.
Request for Project Proposal, Page 5, Paragraph 17.x. For proposal pricing purposes, should offerors assume full-service clinical trial support, including investigational product (IP) packaging and distribution, but excluding laboratory services, for one Phase II trial and two Phase I trials?	Offeror should assume full-service clinical trial support, including IP packaging and distribution, and including laboratory services. Offeror should include a menu of priced options with an assumption of 3 phase I clinical trials and 1 phase 2 clinical trial. Consider the following assumptions: • Phase 1 study will enroll 40 participants • Phase 2 study will enroll 150 participants • Geographic scope is mainly the continental United States, but could potentially include global clinical sites should the need arise • Studies will be conducted at clinical sites and Military Treatment Facilities (MTFs) • Studies will be FDA regulated • Studies may require laboratory specimen collection and processing
W911SR-26-9-CADENCC_RPP, number 1, page 1. General reference to Other Transaction Authority (OTA). Is it possible to share a template of the Other Transaction Authority agreement that might form the basis of a contract with a successful offeror?	Not available at this time.

Attachment 1 – W911SR-26-9CADENCC Statement of Objectives, Security and Classified Data, page 6. The Security and Classified Data Section of the Statement of Objectives, page 6 states, “Any information/data generated under this agreement will be designated Unclassified (U) and is subject to the safeguarding and reporting requirements of the base Other Transaction Agreement Article XVII. Data generated under this contract are considered DoW Controlled Unclassified Information (CUI)…”. Please clarify if the contract data will be considered CUI or standard unclassified information?	Contract data will generally be considered standard unclassified information, but there may be instances where data generated is CUI, in which case the contractor will be expected to follow CUI safeguards.
W911SR-26-9-CADENCC_RPP, number 16, Submissions, page 4. Under Submissions on page 4 of the RPP, it states, “The page limit is 10 pages. Cover page, ROM, and WBS will not be considered in the total page count. Any supplemental attachments outside of the ROM and WBS will count against the 10 page limit. Any additional pages exceeding 10 pages will not be considered.” The RPP specifies that as part of the submission package, the offeror should include a ROM and WBS. With no protocols available at this time and limited study details, please confirm if costing estimates and a WBS are required.	To be removed. Repeat question.
W911SR-26-9-CADENCC_RPP, number 16, Submissions, page 4. Under Submissions on page 4 of the RPP, it states, “The page limit is 10 pages. Cover page, ROM, and WBS will not be considered in the total page count. Any supplemental attachments outside of the ROM and WBS will count against the 10 page limit. Any additional pages exceeding 10 pages will not be considered.” If a ROM does need to be included in the submission package, can the government please clarify the scope of the estimate. Which of the following, should the offeror include in the budget o Annual administrative budget o Mock Ph 1 study budget o Mock Ph 2 study budget If the ROM includes mock studies, please provide high-level study specifications.	The offeror should include all of the aforementioned, with the phase I study budget differentiated between a phase 1a and a phase 1b .

W911SR-26-9-CADENCC_RPP, number 17 viii, Key Personnel Qualifications, page 5. In the Evaluation Factors of the RPP document, on page 5, it states, "Key Personnel Qualifications: Document the qualifications, capabilities and experience of the proposed Project Manager and other key personnel in sufficient details to demonstrate that the proposed staff has the knowledge and skills to achieve the proposed objectives." Should the offeror provide CVs for the proposed key personnel? If so, please confirm CVs will not be considered in the total page count.	Yes, CVs should be included for key personnel, and will not be included in the page count .
Attachment 1 – W911SR-26-9CADENCC Statement of Objectives, Section 3c, Clinical Trial Execution, page 3. Section 3c, Clinical Trial Execution, page 3. Are there specific decentralized capabilities that are considered critical to the CADENCC program (e.g., telehealth, eConsent, home health visits, remote sample collection, wearable devices, eCOA/ePRO, direct-to-patient shipments, mobile research units, or other digital health technologies)?	CADENCC highly encourages the use of decentralized approaches and technologies in study execution, which may include the aforementioned and will be dependent upon the study conducted. Given the potential breadth of clinical studies that may be conducted under CADENCC, we are unable to specify decentralized strategies and encourage you to provide your experiences and capabilities in these strategies.
Attachment 1 – W911SR-26-9CADENCC Statement of Objectives, Section 3c, Clinical Trial Execution, page 3. Section 3c, Clinical Trial Execution, page 3. Can additional planning assumptions be provided regarding anticipated study volume, participant enrollment, geographic scope, and overall study requirements?	Consider the following assumptions: •Phase 1 study will enroll 40 participants •Phase 2 study will enroll 150 participants •Geographic scope is mainly the continental United States, but could potentially include global clinical sites should the need arise •Studies will be conducted at clinical sites and Military Treatment Facilities (MTFs) •Studies will be FDA regulated •Studies may require laboratory specimen collection and processing
Attachment 1 – W911SR-26-9CADENCC Statement of Objectives, Section 3c, Clinical Trial Execution, page 3. Section 3c, Clinical Trial Execution, page 3. Can further details be shared regarding the expected data collection strategy, including whether remote assessments, digital endpoints, wearable data, eCOA/ePRO, laboratory data, or other decentralized data sources are anticipated?	CADENCC highly encourages the use of decentralized approaches and technologies in study execution, which may include the aforementioned and will be dependent upon the study conducted. Given the potential breadth of clinical studies that may be conducted under CADENCC, we are unable to specify data collection strategies and encourage you to provide your experiences and capabilities in data collection strategies.