CADENCC Statement of Objectives

Description of Project

The Capability Program Executive for Chemical, Biological, Radiological and Nuclear Defense (CPE CBRND) Joint Project Lead Enabling Technologies (JPL ET) enables the rapid development, manufacture, and fielding of safe and effective medical solutions across the full product spectrum, including development, clinical trials, manufacturing, and validated biological threat detection materials. The objective of Chemical, Biological, Radiological and Nuclear Advance Defense Enabling Network and Clinical Capability (CADENCC) is to develop an enabling capability that will accelerate clinical trial startup through implementation of Master Protocols, innovative technologies that support decentralized trial operations and augment data collection and analysis, and establishment of a pre-positioned clinical trial site network enabling CBRN defense readiness. CADENCC will primarily conduct Phase I/Phase II clinical trials for pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP), and early treatment products which may be under Animal Rule.

Project Objectives

The Offeror shall provide the necessary qualified personnel, facilities, material, equipment, and services to perform the tasks outlined below. The Offeror and any subcontractors are expected to apply relevant Food and Drug Administration (FDA) and Department of War (DoW) policies, regulations, guidance, and International Council for Harmonization (ICH), Good Clinical Practice (GCP), Good Clinical Lab Practice (GCLP) and Good Laboratory Practice (GLP) best practices in the execution of clinical trials.

1. General Capabilities

- The Offeror shall be compliant with ICH and GCP guidelines.
- The Offeror shall have demonstrated capability in executing clinical trials at military clinical sites or Military Treatment Facilities (MTFs).
- The Offeror shall have experience in collaborating with the US Government (USG), DoW, and other government partners.
- The Offeror shall have experience conducting and/or managing clinical trial laboratory activities where necessary, which may include but are not limited to specimen collection, specimen processing, assays, pharmacokinetic (PK) studies, biomarker studies, and others following GCLP best practices.

- The Offeror may be asked to serve as a product sponsor or coordinate with the Office of the Surgeon General (OTSG) when the government is the product sponsor.

2. Regulatory Capabilities

- The Offeror shall have demonstrated experience with FDA Investigational New Drug (IND) submissions, including collaborating with the FDA on pre-INDs, INDs and conducting product-related meetings.
    - Note that the Offeror may be asked to coordinate with product sponsors for IND-related activities for study protocols; for example, if a Master Protocol is established and a new study cohort needs to be executed under the Master Protocol for a specific product.
- The Offeror shall have experience with Institutional Review Boards (IRBs), scientific review boards, and other review boards related to Human Subject Research.
- The Offeror shall have experience with the DoW Office of Human Research Oversight (OHRO).
- The Offeror shall have experience with international, national, and local regulations and requirements for the execution of global clinical trials.

3. Clinical Research Capabilities

- The Offeror shall possess the capabilities to execute start-to-finish Phase 1 and 2 clinical trials (See Tasks). The Offeror shall possess and/or have demonstrated experience with decentralized clinical trial capabilities.

3a. Master Protocol Development

- The Offeror shall have demonstrated experience in developing syndromic or modality-based umbrella, basket, platform, or similar adaptive clinical trial master protocols.
- The Offeror shall have experience in amending master protocols for product onboarding and/or offboarding.

3b. Clinical Trial Site Network

- The Offeror shall have demonstrated experience in developing and maintaining a clinical trial site network.
- The Offeror shall have demonstrated coverage of the Continental United States (CONUS) with clinical sites, to include Military Treatment Facilities, and experience with clinical sites Outside the Continental United States (OCONUS).
- The Offeror shall have demonstrated experience in clinical site validation, selection, stand-up as it relates to a clinical trial site network.

3c. Clinical Trial Execution

- The Offeror shall have demonstrated experience in executing Phase I and Phase 2 clinical trials from study design to delivery of the Trial Master File.
- The Offeror shall have demonstrated experience in using methodologies or technologies, digital or otherwise, that enable decentralized clinical trials.
- The Offeror shall have demonstrated experience in clinical site selection, including feasibility studies, site training, and site initiation.
    - The Offeror shall demonstrate continuous monitoring capabilities for GCP.
- The Offeror shall have demonstrated experience in participant recruitment and retention, including multi-venue recruitment pathways.

3d. Clinical Data Analysis and Reporting

- The Offeror shall have demonstrated experience in developing and executing Statistical Analysis Plans (SAPs).
    - Offeror shall demonstrate availability of statistical expertise in the event of rapid pivots in protocol design.
- The Offeror shall have demonstrated experience in data collection methodologies, data quality, and data monitoring.
- The Offeror shall have experience in collecting and assessing drug safety information as it relates to clinical trial conduct; i.e. adverse events.
- The Offeror shall have demonstrated experience with developing and operating Drug Safety and Monitoring Boards (DSMBs) and with conducting interim analyses.

3e. Capability Analysis and Reporting

- The Offeror shall have experience in measuring processes, analyzing workflows, and implementing process improvements as it relates to clinical trials executed as a part of this program.

Options

The Government may choose to exercise the following options at its discretion.

1. Digital Technology Capabilities

- The Offeror shall have experience in implementing digital technologies, which may include but is not limited to AI tools and workflows, that improve and accelerate clinical trial execution.

2. Clinical Trials for Additional Products of Interest

- The Offeror may be required to take on additional clinical trials for other products at the discretion of the Government.

Program Management Objectives

1. The Offeror will provide dedicated project manager(s), clinical project team lead(s), and an alliance manager, and include representatives from the major functional areas involved in the project, including clinical site network, study design, clinical trial data management, pharmacovigilance, and regulatory functions. Several project plans, including Project Management, Data Quality, Risk Management and a Communications plan, will be drafted, reviewed, and ultimately approved by the Government. The project management and communication plans will identify project stakeholders, summarize roles and responsibilities of project team members, outline format and frequency of communications/meetings, describe escalation plans, and outline the project risk management strategy. Additional plans may be required per the requirements of clinical trial conduction, including Statistical Analysis Plan, Data Monitoring and Management Plan, and others as deemed necessary by the Government.

2. The Offeror will provide for meeting logistics, including meeting invitations, compiling agenda topics, creating minutes, and tracking action items, decisions and risks. A kick-off meeting will occur prior to the initiation of the project.

3. Document management will be executed via a mutually agreed upon structure, with documents ultimately reviewed and approved by the Government, in coordination with the Offeror, as applicable. Documents (i.e., reports, protocols, records, etc.) that are provided for Government review and/or approval, will be returned to the Government within a 2-week period of receipt, with the exception of documents not on critical path or comprehensive documents which require additional time. Longer review periods shall be determined by the Government. The Government/Offeror shall respond with comments or acceptance 15 calendar days following receipt of the document. The final document with incorporated changes shall be submitted to the Government, with written acceptance to follow.

4. The Offeror will manage all meetings with the purpose of reviewing data, overall project status, milestones, actions, the integrated project timeline, and next steps. Project milestones, as will be laid out in the Statement of Work, will be closely monitored by the Offeror, tracked on the integrated timeline, and discussed during team meetings. If the project team has identified a decision point, the meeting will be structured to ensure the attendance of decision-makers, as well as to ensure the project team has the appropriate information to inform decisions. The Offeror will provide for all meeting

logistics, including meeting invitations, compiling agenda topics, creating minutes, and tracking action items and decisions. The Offeror will monitor and report the status of the project, including dashboards, risk registers, action trackers, decision trackers, Responsible, Accountable, Consulted, and Informed (RACI) charts, and lessons learned tools.

5. The Offeror will provide all necessary functions to support effective Project Management, to include a Kick-Off Meeting, Monthly Integrated Master Schedule (IMS) and Work Breakdown Structure (WBS) updates, regular (weekly, or as otherwise agreed upon) and ad hoc Progress Meetings/Reports, Monthly Expenditure Reporting (cumulative milestone liquidation), Subcontractor Management, Risk Management, Technology Transfer Monitoring, and Integrated Process Team (IPT) participation. Project Management activities will be closely coordinated with the Quality Management team. The Offeror will also include Regulatory Management, including coordinating participation of Government representatives in FDA meetings, submissions, and communications. The Offeror will provide all necessary project deliverables, such as Quarterly Technical and Business Reports, Annual Technical and Business Reports, Final Technical and Business Report, Interim and Final Patent Reports, Public Law (PL) 115-92 Sponsor Authorization Letter (if appropriate), and any other deliverable data or prototypes described above.

Special Requirements

Travel

1. Travel will be commensurate to the requirements of clinical trial conduct as proposed by the Offeror and accepted by the Government. Travel may include, and are not limited to, the following:
   - Site Feasibility or Training Visits
   - Site Initiation Visits
   - Site Monitoring Visits
   - Site Closeout Visits

Government Furnished Property

Government Property. The FDA-regulated products and other biological and pharmaceutical related material stored, shipped, received and retrieved remains property of the United States Government. All property shall be documented and maintained in accordance with the terms and conditions of the contract to include the PWS. All property

shall be secured in accordance with the requirements specified herein, and no property without express permission from the AOR shall have access to this product.

Other Government Contracts

The Offeror shall address other Government contracts that relate to the proposed development effort, including those with agencies outside the DoW. This avoids duplicity in effort and allows cross-Government coordination.

Security and Classified Data

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) and fall under ITAR 120.10 whose export is restricted by the Arms Export Control Act (Title 22, U.S.C. Sec 2778, et seq.) Violations of United States export laws are subject to severe criminal penalties.

Data Rights

Data rights will be negotiated for unlimited rights to data generated with DoW funding for data furnished to or developed for the Government under an agreement.

Intellectual Property Rights

Offeror and Government Intellectual Property (IP) rights shall be retained by each party as it pertains to their own materials, technical data (as defined in 22 C.F.R. § 120.10), technology, information, documents, or know-how—or potential rights, such as issued patents, patent applications, invention disclosures, or other written documentation—that exist prior to execution of any agreements between Offeror and Government.

Government rights will be negotiated for certain IP rights related to work completed as a part of the agreement.