KAIVA TECH, LLC
CAGE: 8N8J5
DUNS: 117565592
UEI: LJHDHAE4FB75

DRT STRATEGIES, INC
CAGE: 3PZT2
DUNS: 142428783

PUBLIC HEALTH

Team Capabilities

Kaiva Tech & DRT combine to create multi-disciplined project teams to solve complex problems. Together we bring the right experts in science, health, & technology to resolve modern public health challenges.

OUR CREDENTIALS

SBA U.S. Small Business Administration 8(a) Certified

HUBZone CERTIFIED

CMMI DEV /3

ISO 20000 Certified · ISO 27001:2013 COMPANY · ISO 27001 Certified · ISO 9001:2015 COMPANY

Our Services

We partner with Federal Health agencies to support the mission of improving health safety, advancing public health domestically and abroad, and responding to public health emergencies.

Data Governance

Develop governance processes to support adoption of health-related data standards & develop data strategy implementation plans that align with The Federal Data Strategy.

Public Health Communications

Promote & advance health information to the public using digital services & web analytics to maximize customer experience.

Public Health Research & Analysis

Public health analysts advancing health research in areas such as polio, amyotrophic lateral sclerosis (ALS), & disease transfer.

Medical Writing, Editing & Publishing

Medical literacy experts with backgrounds in epidemiology, neuroscience, & public health to assist in the drafting & release of health & medical content to the public.

Public Health Education, Training & Community Outreach

Support public health communication & campaigns through web content, graphics support, & training for health-IT systems.

Regulatory Review Support & Analysis

Understanding of pre-market regulatory review processes & post-market surveillance for regulated health products.

Clinical Data Analysis

Apply computational tools such as SAS, R, & Python to review clinical data studies for efficacy & safety analysis.

Health Emergency Response

Domestic & international deployments to gather research in response to health emergencies such as Ebola. COVID-19 support for emergency-use-authorization of drugs & vaccines, & development of the CDC COVID Tracker.

KAIVA TECH, LLC
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DRT STRATEGIES, INC
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AWARD PROCESS

Qualified Native American Tribal 8(a) businesses can be awarded sole-source contracts up to $100M for DoD & up to $25M for federal & civilian agencies, without J&A, per the revision of Section 811 of the NDAA.

AGENCY PROGRAM MANAGER
- Establishes Requirement
- Prepares SOW & Procurement Request
- Identifies 8(a) Firm - Market Research

BUDGET OFFICER
- Authorizes Funding

CONTRACTING OFFICER
- Identifies 8(a) Firm as the most capable
- Offers the requirement to the SBA for the 8(a) Firm

SBA
- Accepts requirements on behalf of the 8(a) Firm
- Authorizes agency to conduct negotiations with 8(a) Firm

CONTRACTING OFFICER
- Issues RFP to the 8(a) Firm

8(a) FIRM
- Submits technical and cost proposal to the Contracting Officer in response to the RFP

CONTRACTING OFFICER
- Performs technical and price analysis

8(a) FIRM
- Negotiates final price and deliverables with the Contracting Officer

CONTRACTING AWARD
- Contracting Officer assembles contract and forwards to SBA
- Government Agency, SBA and 8(a) Firm executes contract

Unlimited Sole Source Set-Aside Contract Value Authority

FAR 19.805 Competitive 8(a); 19.805-1 General

Where an acquisition exceeds the competitive threshold ($4M), the SBA may accept the requirement for a sole source 8(a) award if the SBA accepts the requirement on behalf of a concern owned by an Indian tribe or Alaska Native Corporation.

Past Performance FAR

FAR 15.305(2)(iii)

Past Perfomance information is one indicator of an offerer's ability to perform the contract successfully. The solicitation provides offerors an opportunity to indentify past or current contracts relevant to the requirement and evaluate problems encountered on the identified contracts and the offeror's corrective actions.

Our Clients

& many more

SBA Business Opportunity Specialist

SCOTT CARLSON
U.S. Small Business Administration
Utah District Office

scott.carlson@sba.gov
C: 801-657-1371

Past Performances

Center for Biologics Evaluation and Research (CBER) COVID-19 Medical Writing & Editing Support

DRT Strategies, Inc. (DRT) provides scientific writers and editors, and data analysts to support two offices, Office of Vaccines Research and Review and Office of Biostatistics and Epidemiology, with scientific writing support for the preparation of review memoranda, advisory committee briefing documents, and other associated work product related to COVID-19 vaccine Emergency Use Authorization (EUA) and Biologic License Applications (BLA) submissions. This includes creating data tables, populating those tables with data derived from regulatory submissions, and conducting functional and technical analysis.

DRT's expert staff understands the review processes and concepts central to the review of vaccines and related biological products and helps establish standard practices and templates used for medical editing/writing of regulatory documents. We ensure consistency and appropriate formatting, ensure compliance with Section 508 requirements for reader accessibility, and assist with drafting portions of the documents according to template instructions and examples. We conduct quality reviews using prepared quality control checklists and support the document finalization process. We also prepare risk and benefit analysis review and clinical review memos. Under this contract, DRT has supported the EUA advisory committee meeting briefing documents for the Pfizer COVID-19 Vaccine, Moderna COVID-19 Vaccine, and Janssen COVID-19 Vaccine.

Center for Drug Evaluation & Research (CDER) Drug Review & Scientific Reporting Program Support Services

In 2017, the Food and Drug Administration began its New Drugs Regulatory Program Modernization initiative. The modernization includes process and documentation improvements for reviewing marketing application documents within the Office of New Drugs (OND). DRT Strategies, Inc (DRT) provides support for drug application reviews including business analysis and program support, creation of technical documentation, and operational and advisory support. DRT provides writing and editing support, both editorial and scientific in nature, to streamline the drug regulatory review processes, particularly in Phases 4 and 5 of CDER's 21st Century Review Process. As one of the more complicated and lengthier phases of the overall process, successful reviews require coordination with many inter-disciplinary stakeholders on their numerous input and feedback. This includes information received in support of the electronic and paper regulatory submissions that are submitted to CDER for review and CDER generated data and documents produced in support of the regulatory review process.

Furthermore, we provide operational support for the Medical Policy and Program Review Council and prepare FDA workshop summaries. DRT is also instrumental in supporting and tracking the publication of manuscripts by FDA scientists.

Center for Drug Evaluation & Research (CDER) OND Modernizing the Science of Safety Data Analyses

The CDER Office of New Drugs (OND) includes a team of clinical data scientists to support OND's review of New Drug Applications (NDA) and Biologic License Applications (BLA). DRT provides clinical data scientists to support the rigorous assessment of submitted safety data to ensure the clinical safety data sufficiency and integrity, verifying clinical safety results proposed by sponsors, and creating preliminary clinical safety analyses.

DRT has a team of clinical data scientists with PhDs that interact with FDA stakeholders including the OND Clinical Data Scientist Team by providing subject matter expertise in assessing background packages and sample safety datasets to assess the appropriateness of controlled terminology and safety dataset structure. This includes developing Safety Data Analysis Plans (SDAP) and applying computational skills to include R and/or Python to support the clinical review team with preliminary safety analyses and the generation of requested safety tables and figures based on the SDAP. We conduct safety analyses for Integrated Review Applications to reduce burden on medical officers so they can focus on the regulatory decisions, which helps OND meet its mission.

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Past Performances

Internal Revenue Service (IRS) Application Development Data Delivery Services (AD:DDS) Division Security Engineering Support

The Data Delivery Services (DDS) branch of the Internal Revenue Service's Application Development division contracted with Kaiva Technologies* to ensure the integration of adequate security and privacy protections into its application development lifecycle. The DDS branch is responsible for development activities associated with the IRS' most critical IT assets. Therefore, secure development and delivery of these systems is of critical importance to ensuring the success of the IRS' mission. Kaiva Technologies provided the up-front security engineering and privacy impact analysis support to DDS ensuring that critical IRS systems were developed with adequate security and privacy controls integrated throughout the system development lifecycle in accordance with Office of Management and Budget (OMB), Department of Treasury, and IRS policy requirements.

KPMG NIST SP 800-171 Compliance Assessment & Controlled Unclassified Information Protection Program Implementation

The top rated "Big 4" accounting firm KPMG, LLP engaged Kaiva Technologies to complete an assessment of their global information systems for compliance with NIST Special Publication 800-171, Protecting Controlled Unclassified Information in Nonfederal Systems and Organizations, within 9 months to meet their expedited compliance deadline. Major components of this effort included leveraging our firm's expertise in NIST compliance to interpret and translate the 800-171 controls into understandable terms and, where possible, relating them to KPMG's existing security architecture to meet compliance requirements; developing system security plans documenting control implementation; developing assessment plans and executing controls assessments; documenting assessment findings in security assessment reports; and developing plans of action and milestones for finding mitigation. Further, our scope also included the development of a risk-based continuous compliance program which enabled the Firm's leadership to make informed decisions regarding how to respond to threats to the CUI data processed by its information systems.

USSOUTHCOM Security Support Services

Kaiva Technologies's team supports USSOUTHCOM's mission by developing, implementing, and overseeing security management programs within the headquarters (HQ) and throughout USSOUTHCOM's area of responsibility (AOR); which includes Central and South America, the Caribbean, and the adjacent waters of the Pacific and Atlantic Oceans and the Gulf of Mexico. Our team provides security service support operations such as, but not limited to, drafting, and reviewing policy memos, plans, SOPs, conducting inspections, access control, and manning the Security Help Desk needed to support USSOUTHCOM Headquarters in Miami Florida and it's supporting facilities.

Washington Headquarters Services (WHS) / Joint Services Provider (JSP) Admin Support Services

The Joint Service Provider (JSP) is responsible for the design, development, implementation, management and operation of Pentagon-wide enterprise information technology infrastructure services (networking, operating systems, applications, databases, communications software/hardware, desktops) engineering support, information technology/management, continuity of operations and information assurance. The support was to provide administrative and human resource support including internal and external communications, internal management control program, and support for leadership support in a wide range of DoD information management initiatives.

*TRUE Information Assurance LLC is now Kaiva Technologies