

Capabilities Statement



Klote Medical Research Advisors, LLC

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EUI: HFE3CBXZSMA8

CAGE Code: 13A47

Certified: WOSB, VOSB, SDVOSB

NAICS:	PSCs:
541690	B537
541611	R408
	R425
	R499
	AJ12

Company Overview

Klote Medical Research Advisors is a dedicated consulting firm committed to advancing medical science through expert guidance and strategic support for research initiatives. Founded in 2025, with Dr. Molly Klote as President & CEO, our mission is to empower researchers, pharmaceutical companies, biotechnology firms, non-profit corporations, and academic institutions to navigate the complexities of medical research from conceptualization to publication and beyond. We provide specialized advisory services designed to optimize research operations infrastructure, ensure regulatory compliance, and accelerate the translation of scientific discoveries into impactful healthcare solutions.

Core Competencies

- * **Clinical Trial Design & Oversight:** Expert consultation on study protocol development, patient recruitment strategies, data collection methodologies, and trial management to ensure robust and ethical clinical research.
- * **Regulatory Strategy & Compliance:** Guidance on navigating complex regulatory pathways (e.g., FDA, OHRP, HIPAA) and adherence to Good Clinical Practice (GCP) and other industry standards.
- * **Research Project Management:** Comprehensive project coordination, timeline management, resource allocation, and risk mitigation to ensure efficient and timely project completion.
- * **Research Operations and Regulatory Education & Training:** Development and delivery of specialized training programs for researchers, clinical staff, IRBs, and industry professionals on best practices.

Differentiators

- * **Deep Expertise:** Led by Dr. Klote, 36+ years federal experience, research policymaker in DOD, VA, and HHS.
- * **Client-Centric Approach:** We prioritize understanding our clients' unique challenges and objectives, delivering customized, results-oriented solutions.
- * **Innovation & Best Practices:** Committed to integrating the latest scientific advancements and industry best practices into our advisory services.
- * **Ethical & Compliant:** Adherence to the highest ethical standards and regulatory compliance in all aspects of medical research.
- * **Tailored Solutions:** Flexible and scalable services designed to meet the specific requirements of individual projects, from nascent startups to large established organizations.

Point of Contact:

Dr. Molly Klote

President & CEO

Klote Medical Research Advisors, LLC

Expertise

- Federal Policy (OHRP, FDA, HIPAA)
- Research Efficiency
- Decentralized Clinical Trials
- Compliance
- IRB Operations
- Complex Innovative Designs
- Leveraging Technology/AI
- Innovation
- Institutional Policy
- Research Program Review