NEWS RELEASE

Katherine ("Katie") Willett, MS, Joins Pittsburgh-area-based Contract Research Organization, Clinical Research Strategies, LLC as Clinical and Regulatory Affairs Project Lead

Pittsburgh, PA – May 10, 2021. Clinical Research Strategies, LLC ("CRS"), a Pittsburgh-area-based, US-owned and operated contract research organization (CRO) and executive management consultancy for the life sciences industry is pleased to announce the addition of **Katie Willett**, MS, Clinical and Regulatory Affairs Project Lead, to the firm. Ms. Willett earned her master's degree from the Chatham University in Human Biology and joins the team as an experienced senior research manager in the University of Pittsburgh's Department of Immunology, Center for Vaccine Research. Ms. Willett is completing a Master of Science in Law degree with a focused interest in business law and corporate compliance, biotechnology, intellectual property and patent law, legislation and regulation.

Photo by *Jen Worley*

Most recently, Ms. Willett helped lead and manage scientists focusing on vaccine development for potential biological threats and emerging pathogens including SARS-CoV2, Francisella tularensis, Equine Encephalitic Viruses, Highly Pathogenic Avian Influenza (H5N1), as well as seasonal strains of influenza, Rift Valley Fever Virus, Yersinia pestis, Burkholderia, and Klebsiella pneumonia, and has contributed to significant number of publications and presentations. Her work is particularly important for the firm's early phase clinical trials program in infectious diseases and Investigational New Drug (IND) applications and in vitro diagnostics development.

Prior to her more recent work, Ms. Willett was a senior laboratory manager for the University of Pittsburgh's Department of Urology in the School of Medicine, spearheading grants and publications supported by the U.S. Department of Defense (DoD), in collaboration with Pitt's Drug Discovery Institute and high throughput small molecule screening which resulted in a therapeutic nuclear androgen receptor antagonist currently being studied for use in prostate cancer treatment.

"Katie adds an impressive body of work in U.S. federal grants, vaccine development, urology, cancer, trauma, and surgery. In addition, her 20-plus years of experience coupled with her pursuits in legal studies, compliance, and regulatory reform will prove to be an exceptional value-add to our team and to our clients," says Alethea Wieland, president and co-founder.

About Clinical Research Strategies, LLC: CRS is a specialty CRO and executive management consulting firm that fits-for-purpose veteran life sciences executives, attorneys, regulatory scientists and strategists, clinical operations, project management, quality assurance engineers, and sales and marketing teams to take on the biggest challenges for start-up, mid-sized, and Top-50 life sciences companies, many of whom are facing complex regulatory reform or are developing novel, first-in-class drugs, biologics, diagnostics and medical devices, or software as a medical device (SaMD). Service areas are clinical trials, Functional Service Provider (FSP) models, selection and management of CROs, regulatory compliance strategy and submissions, QMS, EU MDR and GDPR, rescue trials, TMF, risk mitigation and remediation, training high-performing teams, staffing solutions, and decentralized trials.

Indications represented are precision medicine, immuno-oncology, central nervous system, infectious diseases, respiratory diseases, orthopedics, de novo devices, digital health and mobile apps, reproductive health, regenerative medicine, cardiology, major depressive disorder, opioid-sparing pain, cannabis, radiology, and critical care. CRS is a qualified service provider for federal grants.

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