

NEWS RELEASE

Lauren Long, MS, PMP, Joins Pittsburgh-area-based Contract Research Organization, Clinical Research Strategies, LLC as Senior Clinical and Regulatory Affairs Project Lead

Pittsburgh, PA – May 11, 2021. Clinical Research Strategies, LLC ("CRS"), a Pittsburgh-area-based, Usowned and operated contract research organization (CRO) and executive management consultancy for the life sciences industry is pleased to announce the addition of **Lauren Long**, MS, PMP, Senior Clinical and Regulatory Affairs Project Lead, to the firm. Ms. Long earned her master's degree from the University of Maryland in Neuroscience and joins the team as a certified Project Management Professional (PMP) with 8+ years of experience in pharmaceutical interventional clinical research and 6+ years from a large Contract Research Organization (CRO). Ms. Long contributed to a landmark article in late 2019, entitled, "Blockchain Compliance by Design: Regulatory Considerations for Blockchain in Clinical Research," with Wendy Charles, PhD, Sean Manion, PhD, and Natalie Marler, MEd.



Ms. Long has expertise in life cycle risk management, trial management, team-building, revenue recognition, and both vendor and client relationships. Her experience includes Early Phase trials in Healthy Normal Volunteers; Non-Medicated Device Trials, and Trial Designs — First-In-Man/First-In-Human, Drug-Drug Interaction, Food Effect, Thorough QT/QTc, Bioequivalence, Bioavailability, Pharmacokinetics / Pharmacodynamics / Pharmacogenetics, as well as later phase clinical trials.

Photo by Jen Worley

"Lauren has impressive credentials including with a special focus for us with contributions to a key article in blockchain for life sciences, and we are lucky to have her join our team," says David Link, MBA, Co-founder and Chief Quality and Regulatory Officer. Alethea Wieland, Co-founder and President adds, "Lauren is a rare talent who understands translational research, risk management, the practice of medicine, regulatory reform, technology, and project management to optimize clinical research in a new paradigm for decentralized clinical trials."

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

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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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