NEWS RELEASE

Parul Nisha, PhD, Joins Pittsburgh-Based Contract Research Organization, Clinical Research Strategies, LLC as Director of Clinical and Regulatory Affairs

Pittsburgh, PA – February 15, 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 **Parul Nisha, PhD**, Director of Clinical and Regulatory Affairs, to the firm. Dr. Nisha earned her PhD from Carnegie Mellon University in biological sciences and joins the team as a former NIH fellow whose scientific pursuits include 15+ years in genetics, epigenetics, molecular, and cellular biology research. She also conducted pre-clinical drug development and immunology research at the UPMC Children's Hospital of Pittsburgh. Parul brings significant medical device industry experience from Philips Healthcare, a Top 10 global public healthcare company operating in critical care, ventilation, sleep, respiratory fields, and other therapeutic areas.

Photo by *Jen Worley*

Dr. Nisha has a rare blend of drug development and medical device expertise in all aspects of translational science, federal grants, clinical development and operations, scientific writing, regulatory affairs, and project management. More recently, Dr. Nisha contributed to the updates of 100+ products under the new European Medical Device Regulation (EU MDR) requirements. Dr. Nisha is a senior member and mentor of the Pittsburgh Chapter of **Women in Bio** and remains actively involved with community outreach that fosters programs in STEM.

CRS co-founder and chief quality and regulatory officer, David Link, MBA, remarks, "We are thrilled to have such a high-caliber scientist and clinical leader join us from a large medical device and healthcare giant, and we know Parul's background at the sponsor-manufacturer level with a strong quality and regulatory framework is extremely compatible with the true needs of our clients."

"As the business pipeline grows in novel drug development, digital therapeutics, IVDs, diagnostics, medical device, and decentralized clinical trial sectors, Parul has the credentials, values, and entrepreneurial spirit to help us lead our company to the next level," 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 and mid-sized life sciences companies, many of whom 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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