# NEWS RELEASE

## Jennifer Le, PharmD Joins Pittsburgh-Based Contract Research Organization, Clinical Research Strategies, LLC as Clinical and Regulatory Affairs Project Lead

Pittsburgh, PA – August 1, 2022. 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 **Jennifer Le, PharmD**, Clinical and Regulatory Affairs Project Lead. Dr. Le earned her doctorate of pharmacy from the University of Rhode Island, School of Pharmacy. She recently completed a 5-month long internship with CRS and landed her role by proving exceptional performance, know-how, and character.

Photo by Lorin Backe

Dr. Le has had the fortune of working with the FDA's Office of Biotechnology Products by presenting on the topic of "The Open Insulin Project" to key senior-level policy makers; hosting discussions about biosimilar insulins, regulatory pathways for biologics and biosimilars, manufacturing and intellectual property barriers to producing insulin, and the future of insulin prices in the US; and leveraging primary and secondary literature resources to answer internal and external medical and drug inquiries.

Additionally, Jennifer previously completed significant research projects resulting in presentations at Boston Medical Center (Boston, MA) on medication use evaluation of linagliptin, inappropriate anticoagulation use in patients receiving epidural anesthesia, and pharmacy students on patient care and workload.

CRS CEO and Chief Quality and Regulatory Officer, David Link, MBA, states, "Dr. Le demonstrated her value during an internship with us, and she is a natural fit and leader in our organization."

Alethea Wieland, President of CRS adds, "Jennifer is very bright and compatible with our company. We are excited to promote her skills and effectiveness, and enable her growth in pharmaceutical and device regulatory and clinical affairs."

**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 large 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.

CRS is an inclusive employer and does not discriminate in employment on the basis of race, color, religion, sex, gender identity, national origin, political affiliation, sexual orientation, marital status, disability, genetic information, age, education, membership in an employee organization, parental status, military service, or other non-merit factor. CRS does not tolerate censorship, surveillance, bullying, intimidation, retaliation, discrimination, or harassment of any kind.

**Media Contact:**
Ron MacDonald
Step2 Branding and Design
ronmac@step2branding.com
+1 724.814.4067

Alethea Wieland, President and Founder
Clinical Research Strategies, LLC
alethea@clinicalresearchstrategies.com
+1 724.272.1245